No. 06-

Supreme Court, U.S.
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OFFICE OF THE CLERK

IN THE

Supreme Court of the United States

In Re: TAMOXIFEN CITRATE ANTITRUST LITIGATION

JOBLOVE, ALLIED SERVS., DIV WELFARE FUND, BENNISH, KOONAN, GREAT LAKES HEALTH PLAN INC., LACAVA, DONEGA, SMITH, LOVINGER, WOOLLACOTT, WHITESIDE, PLATT, UNDERWOOD, TEAMSTERS LOCAL 237, LYNCH, CALLAWAY, MALONEY, MECHANICAL CONTRACT, IBEW-NECA LOCAL 505 HEALTH & WELFARE PLAN, A.F. OF L. – A.G.C. BUILDING TRADES WELFARE FUND, SHEET METAL WORKERS LOCAL 441 HEALTH & WELFARE PLAN, LOCAL 1199 NAT'L BENEFIT FUND FOR HEALTH AND HUMAN SERVICES, NEW YORK STATEWIDE SENIOR ACTION COUNCIL, MARKS, BLONSTEIN,

Petitioners,

v.

BARR LABS., INC., ASTRAZENCA PHARMACEUTICALS LP, ZENECA INC., ASTRAZENECA PLC,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Under what circumstances is an agreement by a brand pharmaceutical manufacturer (and patent holder) to share a portion of its future profits with a generic market entrant (and alleged patent infringer), in exchange for the generic's agreement not to market its product, a violation of the antitrust laws?

PARTIES TO THE PROCEEDING

Petitioners, plaintiffs below, are consumers of tamoxifen citrate, third-party payor entities that purchased, paid for, and/or reimbursed for tamoxifen citrate, and a healthcare advocacy group (collectively "Plaintiffs").[1] Respondents, defendants below, are a brand-name pharmaceutical manufacturer, Zeneca, Inc. ("Zeneca"),[2] and a generic pharmaceutical manufacturer, Barr Laboratories, Inc. ("Barr") (collectively "Defendants").

STATEMENT PURSUANT TO RULE 29.6

The only Petitioner in corporate form is Great Lakes Health Plan, Inc. It is an AmeriChoice health plan, a provider of public sector health plans that covers people on Medicaid and other government programs. AmeriChoice is wholly owned by UnitedHealth Group.

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1. The consumer petitioners are: (1) Rebecca Bennish; (2) Maxine Blonstein; (3) Nancy A. Callaway; (4) Helen Donega; (5) Betty Joblove; (6); Karen Jo Koonan; (7) Susan LaCava; (8) Lynn Lovinger; (9) Russella Maloney; (10) Carolene Marks; (11) Carol Platt; (12) Rita Smith; (13) Monica Underwood; (14) Connie Whiteside; and (15) Gail Woollacott. The third-party payor petitioners are : (1) Local 1199 National Benefit Fund for Health and Human Services Employees; (2) Great Lakes Health Plan, Inc.; (3) Allied Services Division Welfare Fund; (4) Patrick J. Lynch as Trustee for the Health and Welfare Fund of the Patrolmen's Benevolent Association of the City of New York and the Retiree Health and Welfare Fund of the Patrolmen's Benevolent Association of the City of New York; (5) IBEW-NECA Local 505 Health & Welfare Plan; (6) A.F. of L. - A.G.C. Building Trades Welfare Fund; (7) Sheet Metal Works Local 441 Health & Welfare Plan; and (8) Teamsters Local 237 Welfare Fund and Teamsters Local 237 Retirees' Benefit Fund. Petitioner New York Statewide Senior Action Council, Inc. is a New York not-for-profit corporation dedicated to helping its members and other vulnerable populations similarly situated gain access to quality, affordable health care.

2. Successor entities to Zeneca, as a result of a 1999 merger, include AstraZeneca Pharmaceuticals LP and AstraZeneca PLC. Reference herein to "Zeneca" includes, where applicable, predecessor and successor entities, including, Imperial Chemical Industries PLC ("ICI"), Zeneca's former parent which once held the patent for tamoxifen.

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Plaintiffs respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Second Circuit.

OPINIONS BELOW

The Court of Appeals' August 10, 2006 amended opinion (Pet. App. 1a-69a) is reported at 466 F.3d 187. That opinion amended the court's November 2, 2005 opinion, which is reported at 429 F.3d 370. The September 14, 2006 order of the Court of Appeals denying rehearing and *en banc* rehearing (Pet. App. 108a-109a) is unreported, as is the September 19, 2006 amended order. The opinion of the District Court granting the Defendants' motions to dismiss (Pet. App. 70a-107a) is reported at 277 F. Supp. 2d 121.

JURISDICTION

The judgment of the Court of Appeals was entered on November 2, 2005. An amended judgment was filed on August 10, 2006. A petition for rehearing was denied on September 14, 2006 and an amended order was filed on September 19, 2006. The jurisdiction of this Court rests on 28 U.S.C. § 1254(1).

STATUTORY PROVISION INVOLVED

Relevant portions of the Sherman Act, 15 U.S.C. §§ 1, 2; the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. N. 98-417, 98 Stat. 1585 (1984) ("Hatch-Waxman Act"); and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, §§ 1101-1104, 1111-1118, 117 Stat. 2066, 2448-2464 (2003) ("2003 Medicare Amendments") are set out in an appendix to this petition. Pet App. 136a-157a.

STATEMENT

This case involves the same legal issue that was raised in *Federal Trade Commission v. Schering-Plough Corp.*, No. 05-273, __ U.S. __, 126 S. Ct. 2929 (Jun. 26, 2006) (denying

certiorari), as well as three other recent petitions,[3] *i.e.*, the appropriate antitrust standard applicable to an agreement between a brand pharmaceutical manufacturer (and patent holder) and a generic market entrant (and alleged patent infringer) whereby the patent holder shares a portion of its future profits with the alleged infringer in exchange for the latter's agreement to not market its competitive product. The three Circuit Courts of Appeals that have addressed the issue have rendered inconsistent and irreconcilable decisions. In *Schering*, the United States (by the Solicitor General) recognized the importance of the issues raised,[4] but opposed the Federal Trade Commission's ("FTC") petition for certiorari because of factual findings unique to that particular case. *See* Brief for the United States as Amicus Curiae in *FTC v. Schering-Plough Corp.*, No. 05-273 (dated May 2006) at 12-13. The same important issues are raised in this case without the complications that caused the Solicitor General to oppose certiorari in *Schering*. The radical divergences between the views taken of these issues by the Second, Sixth and Eleventh Circuits, as well as by antitrust enforcement authorities, continues to create enormous uncertainty as to the controlling law, preventing clarity both in antitrust counseling and in the litigation of frequently recurring antitrust issues in the pharmaceutical field.

The Hatch-Waxman Act, 21 U.S.C. § 355, establishes a process to expedite and facilitate the development, approval and marketing of generic drugs. *See Andrx Pharm., Inc. v.*

3. *Andrx Pharm., Inc. v. Biovail Corp.*, 535 U.S. 931 (2002) (No. 01-1050); *Andrx Pharm., Inc. v. Kroger Co.*, 543 U.S. 939 (2004) (No. 03-779); *Valley Drug Co. v. Geneva Pharm., Inc.*, 543 U.S. 939 (2004) (No. 03-1175).

4. "The petition raises important and complex issues concerning the antitrust treatment of settlements in patent cases, particularly settlements that provide for delayed entry into the market combined with 'reverse' payment from the patent holder to the alleged infringer." Brief for the United States as Amicus Curiae in *FTC v. Schering-Plough Corp.*, No. 05-273 (dated May 2006) at 8.

Biovail Corp., 256 F.3d 799, 801 (D.C. Cir. 2001) ("Congress sought to get generic drugs into the hands of patients at reasonable prices – fast.") (citation omitted). A generic company seeking to market a generic drug must file an Abbreviated New Drug Application ("ANDA") that incorporates the safety and efficacy data developed and previously submitted by the company that produced the original "pioneer" brand-name drug. *See* 21 U.S.C. § 355(j)(2)(A)(iv). If the generic company seeks to enter the market prior to the expiration of patents listed for the pioneer drug, it must include a "Paragraph IV Certification," which is a technical infringement of the patent likely to prompt a patent infringement action. *See* 21 U.S.C. § 355(j)(2)(A)(vii);[5] *see, e.g.*, David A. Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*, 55 Food & Drug L. J. 321, 332 (2000). The central purpose of the Hatch-Waxman Act is to encourage generic manufacturers to bring their competing drugs to market. The Act encourages generic manufacturers to file Paragraph IV certifications and to seek market entry prior to the expiration of patents by rewarding the first applicant to do so with an exclusivity period of at least 180 days before the FDA can approve another generic manufacturer's ANDA. 21 U.S.C. § 355(j)(5)(B)(iv) (providing for a 180 day exclusivity period for the first ANDA-IV filer) (the "Exclusivity Period").

A. Plaintiffs Have Alleged a Horizontal Market-Allocation Agreement That Violates Federal and State Antitrust Law.

These antitrust class actions involve the prescription drug tamoxifen citrate ("tamoxifen"), the most essential drug for the treatment of breast cancer. Zeneca manufactures and markets tamoxifen under the brand-name Nolvadex®. Zeneca's former parent, Imperial Chemical Industries PLC ("ICI"), held the patent for tamoxifen, U.S. Patent 4,536,516 (the "'516 Patent"). In 1987, Barr amended its ANDA for tamoxifen to include a

5. An ANDA with a Paragraph IV Certification is referred to herein as an "ANDA-IV."

Paragraph IV Certification, which prompted a patent infringement suit by ICI (Zeneca's parent which was then the patent holder). In 1992, following a bench trial before Judge Vincent L. Broderick, Barr won – the '516 Patent was held invalid and unenforceable. *Imperial Chem. Indus., PLC v. Barr Labs., Inc.*, 795 F. Supp. 619 (S.D.N.Y. 1992).

This judgment paved the way for a fully competitive market for generic tamoxifen in which Barr would have had a head-start of at least 180 days. While an appeal from the judgment invalidating the patent was pending in the Federal Circuit, Zeneca and ICI, the patent holders, and Barr, the alleged infringer, agreed to preserve the tamoxifen monopoly and share the monopoly rents. *See Imperial Chem. Indus., PLC v. Heumann Pharma GmbH & Co.*, 991 F.2d 811, 1993 WL 118931 (Fed. Cir. 1993) (unpublished disposition).[6] Zeneca and ICI agreed to: (1) pay Barr, the alleged infringer, $21 million; (2) pay Barr's supplier $35.9 million; and (3) supply Barr with Zeneca-manufactured tamoxifen for resale in the United States at a high royalty rate. In return, Barr agreed to: (1) abandon its successful challenge of the tamoxifen patent; (2) withdraw its Paragraph IV Certification to manufacture and market generic tamoxifen prior to the patent's expiration; and, if possible, (3) prevent competitive entry by future generic manufacturers.

Among other claims, Plaintiffs allege that the Agreements unlawfully restrained competition in the market for tamoxifen in violation of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, and analogous state statutes. While a generic drug is usually priced 30% to 80% below its brand-name counterpart, tamoxifen remained a single-source, monopoly product, with Barr distributing unbranded, Zeneca-manufactured tamoxifen at a price 5% less than branded Nolvadex®. Moreover, when subsequent generic manufacturers sought to enter the tamoxifen

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6. The agreement is embodied in Defendants' March 5, 1993 "Confidential Settlement Agreement" and "Distribution and Supply Agreement" (collectively, the "Agreements").

market, Barr, aided by a court decision rejecting the FDA's "successful defense" requirement, claimed the Exclusivity Period and successfully blocked FDA approval of another generic manufacturer's ANDA (*i.e.*, Mylan Pharmaceuticals, Inc. ("Mylan")).

B. The Course of the Proceedings and the Disposition in The District Court.

In 2000 and 2001, numerous antitrust actions challenging Defendants' Agreements were filed in state and federal courts. For the cases filed in federal court, jurisdiction was premised upon 28 U.S.C. §§ 1331, 1337(a), 15 U.S.C. §§ 22 and 26, and supplemental jurisdiction over Plaintiffs' state law claims was premised on 28 U.S.C. § 1367(a). Defendants removed all of the state court actions to federal court. Pursuant to 28 U.S.C. § 1407, the Judicial Panel on Multidistrict Litigation centralized all of the litigations in the United States District Court for the Eastern District of New York, before the Honorable I. Leo Glasser. *In re Tamoxifen Citrate Antitrust Litig.*, 196 F. Supp. 2d 1371 (J.P.M.L. 2001). On August 26, 2002, the district court denied motions to remand certain actions back to state courts. *In re Tamoxifen Citrate Antitrust Litig.*, 222 F. Supp. 2d 326 (E.D.N.Y. 2002).

On February 14, 2002, Plaintiffs filed their Corrected Consolidated Class Action Complaint ("Complaint"). On May 13, 2003, the district court granted Defendants' motions to dismiss under Rule 12(b)(6), Fed. R. Civ. P., holding that Plaintiffs failed to allege a "bad faith" settlement of the underlying patent infringement litigation. Pet. App. 70a-107a. The district court also held that Plaintiffs failed to allege an antitrust injury because the supra-competitive prices paid necessarily derived from the continued validity of the '516 Patent, despite Barr's successful challenge to the patent at the district court level, and not the Agreements. Final judgment was entered on May 21, 2003, and a timely notice of appeal was filed on June 13, 2003.

C. The Disposition by the Second Circuit.

On November 2, 2005, over a forceful dissent (Pet. App. 110a-135a), the majority of the Second Circuit panel affirmed the dismissal of Plaintiffs' case. An amended opinion was entered on August 10, 2006. Pet. App. 1a-69a. The majority of the Second Circuit panel held that a pharmaceutical patent holder is essentially immune from antitrust liability for paying a generic competitor to abandon even a successful patent challenge and stay out of the market, regardless of: (i) the amount of consideration provided to the generic competitor (even if the consideration grossly exceeds the competitor's expected profits in a competitive market); and (ii) the patent's defects or weakness (short of fraud or complete baselessness), so long as the agreement does not expand the facial scope of the rights that the patent would provide if assumed to be valid and enforceable.

REASONS FOR GRANTING THE PETITION

While Petitioners maintain that the Second Circuit's decision is contrary to settled antitrust law, as addressed further below, review by this Court is necessary to reconcile radically conflicting standards adopted by the Courts of Appeals relative to a matter of vital importance to all Americans, *i.e.*, the escalating cost of prescription drugs. The vast disagreements among the Circuits, on an issue of such basic importance, will continue to cause uncertainty, litigation and delays in generic entry, resulting in billions of dollars in overpayments for pharmaceuticals or, sadly, some consumers' inability to afford needed medication.

Brand-name drugs, many of which claim patent protection, account for most of the increase in drug costs. Generic drugs – chemically and pharmacologically identical but lacking a brand-name – are much less costly, on average about half the price of comparable brand-name drugs. Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration; An FTC*

Study 9 (2002), *available at* www.ftc.gov/os/2002/07/genericdrugstudy.pdf. The Hatch-Waxman Act has been successful in expediting the approval and production of generic drugs. However, its remedial purposes have been thwarted by the type of anticompetitive conduct alleged in this case. When generic versions of popular brand-name drugs are launched, the generics quickly capture the bulk of the market, saving consumers billions of dollars. *See* Federal Trade Commission, *Prepared Statement of the Federal Trade Commission before the Special Committee on Aging of the United States Senate on Barriers to Generic Entry*, July 20, 2006 ("FTC July 2006 Statement"), p. 6[7] ("As a result of price competition, as well as the policies of public and private health plans and state laws that encourage the use of generic drugs, generic sellers typically capture anywhere from 44 to 80 percent of branded sales within the first full year after launch of the lower-priced generic product.") (footnote omitted); *Sanofi-Syntholabo v. Apotex Inc.*, No. 02-2255, 2006 WL 2516486, at *25 (S.D.N.Y. Aug. 31, 2006) (generic version of popular brand-name drug Plavix captured 78.4% of sales within three weeks).

A delay in the launch of a generic version of a popular drug forces consumers to pay millions of dollars *a day* in monopoly rents. Thus, brand-name manufacturers have become adept at abusing the Hatch-Waxman regime to block, frustrate and delay generic entry. When all else fails, brand companies can – and often will – pay cash (or other consideration) to forestall competition.[8] In the end, consumers pay more, not less, as a

7. *Available at:*

http://www.ftc.gov/os/2006 07P052103 Barriers to Generic EntryTestimonySenate07202006.pdf

8. *See, e.g., In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003), *aff'g* 105 F. Supp. 2d 682 (E.D. Mich. 2000); *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp.2d 1279 (S.D. Fla. 2005). Generic companies like respondent Barr can, and often will, accept (Cont'd)

result of the patent challenge originally launched under the provisions of the Hatch-Waxman Act.

> These settlements, which appear to be unique to the pharmaceutical industry, occur when a branded company shares a portion of its future profits with a potential generic entrant in exchange for the generic's agreement not to market is product. Although both the brand company and the generic company are better off financially, these settlements restrict competition at the expense of consumers, whose access to lower-priced generic drugs may be deferred for years.

FTC July 2006 Statement, p. 5-6.

Under the Second Circuit's standard, antitrust review of generic exclusion agreements will be limited to: (1) whether infringement claims based on the patent at issue constitute a "sham" or fraud; and (2) whether the agreement is limited to the facial scope of the patent. The Second Circuit's novel rule is far outside the mainstream of judicial and academic analysis of such agreements. Review under the Sixth and Eleventh Circuit standards require markedly different approaches. The Sixth Circuit considers such agreements *per se* illegal. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003). The Eleventh Circuit applies its own test that inquires into the underlying validity of the patent at the time of the exclusion payment before judging the validity of the reverse payment agreement. *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294 (11th Cir.

(Cont'd)
cash in lieu of marketing a competing product. In accepting a payment in excess of what it could have made if it had entered the market with its own product, Barr accepted an offer it could not rationally refuse unless restrained by antitrust considerations. In addition to this case, Barr has accepted exclusion payments for ciprofloxacin, *see In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514 (E.D.N.Y. 2005), and Ovcon 35. *See FTC v. Warner Chilcott Holdings, Inc.*, No. 1:05-cv-021790CKK (D.D.C.).

2003). No other circuit has applied the Second Circuit's approach.

In addition to the inconsistent positions of the Second, Sixth and Eleventh Circuits, the FTC has advanced a "rule of reason" inquiry that does not require direct analysis of the patent merits at all, at least in government enforcement proceedings, but instead focuses on the existence and amount of the reverse payment and other circumstantial factors. *In re Schering-Plough Corp.*, FTC Docket No. 9297, 2003 WL 22989651 (FTC Dec. 8, 2003), *rev'd, Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005) (rejecting the FTC's approach), *cert. denied*, __ U.S. __, 126 S.Ct. 2929 (2006). The United States (through the Solicitor General), has stated that "an appropriate legal standard should take into account the relative likelihood of success of the parties' claims viewed *ex ante*." Brief for the United States as Amicus Curiae in *FTC v. Schering-Plough Corp.*, No. 05-273 (dated May 2006) at 11.

The Court should accept review of this case to resolve the split in circuit authority. The Court could adopt the standard articulated by one of the circuit courts of appeals or government agencies, or possibly establish another, such as those suggested by antitrust scholars.[9] This case is a particularly appropriate vehicle for addressing conflicting standards. The Second Circuit recognized that "the issues presented have been much litigated and appear to retain their vitality." Pet. App. 2a; *see also* Hemphill, 81 N.Y.U. L. Rev. at 1568:

> "The basic settlement structure is simple, though individual settlements offer many variations on the

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9. *See, e.g.*, C. Scott Hemphill, *Paying for Delay*, 81 N.Y.U. L. Rev. 1553 (Nov. 2006) ("Hemphill"). There, Professor Hemphill maintains that the FTC, the Eleventh Circuit and the Second Circuit incorrectly analyze these cases in terms of whether the patent or antitrust laws should be accorded primacy, because: (1) the Hatch-Waxman Act established a regulatory regime that trumps the patent law in that particular context; and (2) the issue is how the antitrust laws should be applied under that regulatory regime (not under the patent laws).

> theme. The generic firm abstains from entry, the innovator agrees to pay the generic firm a large sum, typically in the tens or hundreds of millions of dollars, and the parties agree to dismiss the patent suit."

(Footnote omitted). In *Schering*, the United States (by the Solicitor General) recognized the importance of the issue, but opposed the FTC's petition for certiorari because of factual findings unique to that particular case.

> The court of appeals determined that [brand manufacturer] Schering's $60 million payment to [generic manufacturer] Upsher was not compensation for delayed market entry by Upsher, but was instead an independent and bona fide royalty payment by Schering to license Upsher's products. . . . Unless overturned, that determination forecloses any antitrust challenge to the Upsher settlement, *even under the FTC's theory*.

Brief for the United States as Amicus Curiae in *FTC v. Schering-Plough Corp.*, No. 05-273 (dated May 2006) at 12-13 (emphasis in original); *see also id.* at 15 ("[T]he unusual circumstances surrounding the ESI payment [*i.e.*, payments to another generic manufacturer] suggest that it is unlikely to provide a factual setting conducive to the Court's identification and application of the appropriate legal standard to govern reverse-payment settlements generally.").

In this case, the Court need not afford deference to any factual findings derived from conflicting evidence because, unlike *Schering*, this case was resolved on the face of a pleading by granting a motion to dismiss. The appellate standard of review is *de novo* and the allegations in Plaintiffs' Complaint must be construed in the light most favorable to Plaintiffs. *See, e.g., Allaire Corp. v. Okumus*, 433 F.3d 248, 249-50 (2d Cir. 2006). In addition, courts and commentators have struggled with whether and how to evaluate the patent-holder's likelihood of

success at a patent infringement trial that never occurred because of the exclusion agreement. *Cf. In re Ciprofloxicin Antitrust Litig.*, 363 F. Supp. 2d 514, 531-36 (E.D.N.Y. 2005). Here, however, the patent *was* held invalid, *Imperial Chem. Indus., PLC v. Barr Labs., Inc.*, 795 F. Supp. 619 (S.D.N.Y. 1992), and the generic exclusion agreement here was reached while the case was on appeal from that judgment. *Imperial Chem. Indus., PLC v. Heumann Pharma GmbH & Co.*, 991 F.2d 811, 1993 WL 118931 (Fed. Cir. 1993) (unpublished disposition). Because appellate courts afford deference to factual findings, the range of risks to be evaluated on appeal are narrower than those at trial. *See* Pet. App. 127a-129a (Pooler, J., dissenting).

In counseling against plenary review in *Schering,* the United States (by the Solicitor General) also pointed to the possibility of the potential for eventual review of the *Ciprofloxacin* litigation. Brief for the United States as Amicus Curiae in *FTC v. Schering-Plough Corp.*, No. 05-273 (dated May 2006) at 16. The Second Circuit's decision here is substantially based upon the reasoning of the district court in *Ciprofloxacin,* 363 F. Supp. 2d at 529-538. *See* Pet. App. 48a-53a.

Accordingly, the facts of this case and the rulings below will allow the Court to address the propriety of generic exclusion/reverse payment agreements under the antitrust laws. Absent guidance by this Court, the conflicting circuit court standards leave everyone – the pharmaceutical industry, antitrust regulators, and the purchasers and consumers of pharmaceuticals (*i.e.*, those who ultimately must pay the bill) – in a quandary. This will continue to cause uncertainty and delays in generic entry, resulting in billions of dollars in overpayments for pharmaceuticals or, sadly, some consumers' inability to afford needed medication.

I. The Standard Adopted By the Second Circuit is In Conflict With Standards Articulated by Other Circuits, the Federal Trade Commission and Scholarly Commentators.

According to the Second Circuit, an agreement between a patent holder and an alleged infringer to settle Hatch-Waxman patent litigation cannot violate the antitrust laws so long as the patent litigation was not a fraud, sham or otherwise baseless and the settlement agreement does not impose restrictions on the alleged infringer that extend beyond the alleged scope of the challenged patent. The Second Circuit's holding is that generic exclusion agreements are beyond the reach of antitrust scrutiny, *per se* legal if you will, even if, as here, the patent holder makes substantial payments to the alleged infringer in exchange for the latter's promise to abandon the patent challenge and its efforts to launch a generic product. The Second Circuit recognized that its rule of *per se* legality shields questionable settlements involving "fatally weak" patents, but concluded that the policy favoring settlement is so strong that it trumps antitrust concerns. Pet. App. 49a ("So long as the law encourages settlement, weak patent cases will likely be settled even though such settlements will inevitably protect patent monopolies that are, perhaps, undeserved."). The general preference for settlements must be tempered when settlements have important adverse consequences on third parties. *See* Brief for the United States as Amicus Curiae in *FTC v. Schering-Plough Corp.*, No. 05-273 (dated May 2006) at 8 ("Although public policy wisely encourages settlements of legal disputes, it does not follow that all settlements are consistent with the public interest.") (citation and quotation marks omitted).[10] The two other circuits that have directly addressed "reverse payment" exclusion agreements have reached radically different conclusions.

The Sixth Circuit, in *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003), upheld the trial court's summary

10. *See also* Ronald E. Davis, *Reverse Payments Patent Settlements: A View into the Abyss and a Modest Proposal*, Vol. 21, No. 1, ABA Antitrust Journal 26, 32 (Fall 2006) ("The extreme pro-settlement views of the *Tamoxifen* court and others cannot stand.").

judgment ruling that a reverse payment agreement was *per se* illegal. *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 683 (E.D. Mich. 2000). "There is simply no escaping the conclusion that the Agreement, all of its other conditions and provisions notwithstanding, was, at its core, a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a *per se* illegal restraint of trade." *Id.* at 908. The substantial "reverse payment" made by the patent holder to the patent challenger was the driving force in the Sixth Circuit's reasoning. "It is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competitors *by paying the only potential competitor $40 million per year to stay out of the market.*" *Id.* (emphasis added). The Sixth Circuit's decision of *per se* illegality is irreconcilable with the Second Circuit's holding of *per se* legality, which would render issues such as the size of any "reverse payment" made to the patent challenger legally irrelevant.

The Eleventh Circuit, in *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294 (11th Cir. 2003), reversed a trial court ruling that a "reverse payment" agreement was *per se* illegal. The Eleventh Circuit held that because the "exclusionary power" of the patent needed to be considered, a rule of *per se* liability would be inappropriate "when no court had declared [the brand manufacturer's] patent invalid or unenforceable at the time of the Agreements." *Id.* at 1306 & n.18. From this reasoning, it would follow that a "reverse payment" settlement *is* properly treated as a *per se* antitrust violation when – as in this case – the patent in question *had already been held to be unenforceable* at the time of the challenged agreements. *Valley Drug* held that a fair analysis of the "exclusionary power" of the patent should include such factors as "what lost profits [the brand-name manufacturer] expected from generic competition or what profits [the generics] expected to gain from entry." 344 F.3d at 1310. This is because "the size of the payments might be evidence supporting a claim that the patentee knew that the patent was

procured by fraud, or knew that the patent was invalid, or that there was no objective basis to believe the patent was valid." *Id.* at 1310 n.22. These elements of the *Valley Drug* opinion are irreconcilable with the Second Circuit's key holdings that only a fraudulently procured patent or sham litigation could sufficiently establish weakness of the patent, and that a "reverse payment" of *any* size to the patent challenger is irrelevant.[11] Thus, the amount of the reverse payment could dwarf the profits expected by the generic firm if it succeeded in invalidating the patent and entering the market. Such a payment, held *per se* legal by the Second Circuit, is an offer no rational generic firm could refuse.

Hatch-Waxman Act "reverse payment" agreements have also been a "hot button" issue in antitrust scholarship for years. Academic literature is largely divided between "rule of reason" proponents, on the one hand, and *per se* illegality proponents on the other. No one has argued for *per se* legality, as the dissent points out. Pet. App.123a-126a.[12] Very recently, one of the

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11. The Eleventh Circuit revisited these issues in *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), but made clear that it continues to adhere to *Valley Drug*. *Id.* at 1065 ("We are bound by our decision in *Valley Drug*."). The *Schering* opinion also states that although the mere existence of a "reverse payment" is insufficient to establish unlawfulness, "[t]his alone underscores *the need to evaluate the strength of the patent*." *Id.* (emphasis added).

12. Some academic scholars have written that reverse payment settlements of Hatch-Waxman patent litigation with large payoffs to the alleged infringer should be presumptively anti-competitive. *See* Scott C. Hemphill, *Paying for Delay*, 81 N.Y.U. L. Rev. 1553 (Nov. 2006); Herbert Hovenkamp, *IP and Antitrust*, § 7.4 e2 at 7-38 to 39 (2005 Supp.); Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719 (June 2003); Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 Rand J. Econ. 391 (2003); Jeremy Bulow, *The Gaming of Pharmaceutical Patents, in 4 Innovation Policy and the Economy*, (Adam B. Jaffe et al. eds. 2004); Mark A. Lemley & Carl Shapiro, (Cont'd)

foremost antitrust commentators has expressed the frank view that the reasoning in *In re Ciprofloxicin Antitrust Litig.*, 363 F. Supp. 2d 514 (E.D.N.Y. 2005), on which the Second Circuit opinion is largely based, just "doesn't work under Hatch-Waxman." Herbert Hovenkamp et al., *IP and Antitrust*, § 7.4 at 7-37 (2006 Supp.).

II. The Second Circuit's Decision Has Exacerbated Uncertainty and Confusion Surrounding the Propriety of Generic Exclusion Agreements.

The Hatch-Waxman Act regime promoting ANDA challenges has resulted in pre-patent expiration generic entry on a number of blockbuster drugs, saving consumers billions of dollars. Of the ten best-selling drugs from 2000, at least four – Paxil, Prilosec, Prozac and Zocor – have faced generic competition prior to patent expiration. *See* Hemphill, 81 N.Y.U. L. Rev. at 1567, n.57; FTC July 2006 Statement, p. 11. Prior to the Second Circuit's decision, FTC enforcement actions[13] and

(Cont'd)

Probabilistic Patents, 19 J. Econ. Perspectives 75 (2005); Joseph Farrell & Carl Shapiro, *How Strong Are Weak Patents?* Competition Policy Center Working Paper 05-054 (2005), *available at* http://repositories.cblib.org/iber/cpc/CPC05-54/. Others have argued for application of the rule of reason, Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 Fla. L. Rav. 747, 779-96 (2002); Roger D. Blair & Thomas F. Cotter, *Are Settlements of Patent Disputes Illegal Per Se?*, 47 Antitrust Bull. 491, 534-38 (2002), or for per se illegality. Maureen A. O'Rourke & Joseph F. Brodley, *An Incentives Approach to Patent Settlements*, 87 Minn. L. Rev. 1767, 1781-82 (2003).

13. *See, e.g., In the matter of Hoechst Marion Roussel, Inc., et al.*, No. 9293 Decision and Order (FTC May 8, 2001) (regarding Cardizem CD), *available at http://www.ftc.gov/os/2001/05/hoechstdo.htm; In the matter of Abbott Laboratories, et al.*, No. C-3945, Decision and Order (FTC May 22, 2000) (regarding Hytrin), *available at* http://www.ftc.gov/os/2000/05/c3945.do.htm.

private antitrust litigation[14] had virtually eliminated reverse payment settlements in Hatch-Waxman patent litigation. Section 1112 of the 2003 Medicare Amendments, signed by President Bush on December 8, 2003, requires the submission of generic exclusion agreements to the FTC and Department of Justice, though it does not require their advanced approval.[15] Congress passed this law to "re-emphasize the Hatch-Waxman Act's original intent of enhancing competition, not collusion, between generic and name-brand manufacturers." Brief for Henry A. Waxman as Amicus Curiae in *FTC v. Schering-Plough Corp.*, No. 05-273 (dated Sept. 30, 2005) at 10.

For fiscal year 2004, none of the fourteen reported agreements between brand and generic manufacturers contained a payment from the brand to the generic accompanied by deferred generic entry. *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2004: A Report by The Bureau of Competition* (Jan. 7, 2005), *available at* http://www.ftc.gov/opa/2005/01/drugsettlement.htm. *http://www.ftc.gov/oos/2005/1/050107medicareactrpt.pdf.* In other words, the parties to Hatch-Waxman patent litigation found ways to settle that did not require paying-off the generic manufacturer. For fiscal 2005, there were sixteen settlements and three included payments to the generic companies to defer market entry. The Eleventh Circuit decision in *Schering,* issued in March 2005 (midway through the fiscal year), had opened that door a crack. On April 24, 2006, FTC Commissioner Jon Leibowitz commented that:

> The more recent evidence – though not complete for fiscal year 2006 – is far more disturbing. In the six months following *Tamoxifen*, more than two-thirds of

14. *See, e.g. In re Cardizem CD Antitrust Litig.*, 218 F.R.D. 508 (E.D. Mich. 2003), *aff'd in part and dismissed on other grounds*, 391 F.3d 812 (6th Cir. 2004).

15. Antitrust regulators could bring action challenging generic exclusion agreements, but application of the Second Circuit is standard would largely immunize such agreements from Antitrust scrutiny.

> approximately ten agreements between brands and generics included payment from the brand and an agreement to defer generic entry. In other words, just before the *Schering* and *Tamoxifen*, there were no payments; just after them, this appears to be the new way to do business.

Jon Leibowitz, *Exclusion Payments to Settle Pharmaceutical Patent Cases: They're B-a-a-ack!* (April 24, 2006), *available at* http://www.ftc.gov/speeches/leibowitz/060424 Pharma SpeechACI.pdf; *see also* FTC July 2006 Statement, p. 13-14.

Thus, the Second Circuit's decision has fostered a new era in generic exclusion agreements that keep lower-priced generic drugs *out* of consumers' hands, contrary to the express purposes of the Hatch-Waxman Act. Judge Pooler's dissent – which characterized the majority's "tacit assumption that the settling parties will not act to injure the consumer or competition" as "panglossian" (Pet. App. 125a-126a, n. 37) – has proved prophetic.

III. Contrary to the Second Circuit's Opinion, it is a Violation of the Antitrust Laws For Horizontal Competitors To Enter Agreements That Restrict Output, Allocate Markets and Restrain Price Competition, Even When Patents Are Involved.

Plaintiffs allege that Defendants' Agreements violate the antitrust laws because of a combination of factors, including: (1) the Agreements were entered into after the patent had been held invalid and unenforceable by clear and convincing evidence; (2) the value of the consideration that was provided by Zeneca (the patent holder) to Barr (the alleged infringer) greatly exceeded Barr's litigation costs as well as the expected profits Barr would earn if it entered the market with its own product; and (3) the continuing nature of Defendants' relationship had a continuing adverse effect on other generic manufacturers' efforts to enter the market. Private settlement of patent infringement litigation cannot be deemed an antitrust

safe-haven for horizontal competitors to enter into sweeping output restriction, market allocation and price-fixing agreements. It is well-settled that even holders of valid patents are liable for antitrust violations when they combine with horizontal competitors to exclude competition. *United States v. Singer Mfg. Co.*, 374 U.S. 174, 196-97 (1963) ("[P]ossession of a valid patent or patents does not give the patentee any exemption from the provisions of the Sherman Act beyond the limits of its patent monopoly."); *Andrx*, 256 F.3d at 813 n.15 ("[E]ven a patent-right holder is not immune from antitrust liability."). While it is lawful for patents to be used to protect monopolies, it is not lawful for monopolies to be used to protect patents, which is what the Second Circuit's decision allows.

With the notable exception of the lower courts' decisions here, virtually every court to consider such alleged generic exclusion agreements has, at a minimum, held that plaintiffs stated a claim upon which relief can be granted. *See, e.g., In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003) (interlocutory appeal upholding the district court's denial of motions to dismiss antitrust claims, and upholding partial summary judgment that agreement was *per se* illegal), *aff'g*, 105 F. Supp. 2d 618 (E.D. Mich. 2000) (motion to dismiss ruling) and 105 F. Supp. 2d 682 (E.D. Mich. 2000) (partial summary judgment ruling); *Andrx Pharm., Inc. v. Biovail Corp.*, 256 F.3d 799 (D.D.C. 2001) (vacating dismissal with prejudice and remanding); *Andrx Pharm. Corp. v. Elan Corp.*, 421 F.3d 1227, 1236 (11th Cir. 2005) (agreement between brand and generic manufacturer stated claim for antitrust violation); *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279 (S.D. Fla. 2005) (granting motion for partial summary judgment that agreement was *per se* illegal); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188 (E.D.N.Y. 2003) (granting in part and denying in part motions to dismiss), *but see* 363 F. Supp. 2d 514 (E.D.N.Y. 2005) (granting defendants' motion for summary judgment); *In re Buspirone Patent Litig.*, 185 F. Supp. 2d 363 (S.D.N.Y. 2002) (granting in part and denying in part motions to dismiss).

The Second Circuit did not dispute that Plaintiffs suffered an "injury," but rather, like the district court, held that there was no *antitrust* injury because there was a *lawful* monopoly. *See* Pet. App. 62a ("The Agreement is no doubt 'anticompetitive' the plaintiffs need no additional proof of that. It limited competition between generic tamoxifen and Zeneca's branded product. But, as we have seen, because it did not exceed the scope of the tamoxifen patent, it was not an *unlawful* anticompetitive agreement.") (emphasis in original). Under the Second Circuit's standard, those who improperly acquire patents on drugs will have carte blanche to spend unlimited amounts for the purpose of "buying off" competitors who challenge those patents. In other words, the antitrust laws are completely neutered when pharmaceutical patentees maintain their monopolies through the depth of their pockets, rather than the strength of their patents.

From a legal standpoint, the dissent rightly states that the majority opinion "is not soundly grounded in Supreme Court precedent and is insufficiently protective of the consumer interests safeguarded by the Hatch-Waxman Act and the antitrust laws." Pet. App. 117a. The majority opinion embodies "several subsidiary holdings, conclusions, or assumptions." *Id.* Many errors in them are catalogued *seriatim* in the thoughtful dissent. Pet. App.110a-135a. Without belaboring points made in the dissent, we address below just some of the defects in the Second Circuit's opinion.

A. The *Noerr-Pennington* Doctrine Does Not Apply to Private Settlements of Litigation.

The Second Circuit held that unless the monopoly is extended beyond the patent's alleged scope, a "reverse payment" agreement is actionable only if there is fraud or sham litigation. The Second Circuit thus borrows, as a key element of its standard for "reverse payment" cases, a "fraud or sham" doctrine designed instead to define exceptions to immunity for petitioning under the *Noerr-Pennington* doctrine. *Eastern R.R. Presidents'*

Conference v. Noerr Motor Freight Inc., 365 U.S. 127 (1961); *United Mine Workers v. Pennington*, 381 U.S. 657 (1965). The dissent rightly states that it is "ill-advised," and at odds with Supreme Court law, to "import" those doctrines from government petitioning activity protected by the First Amendment into an inapposite context. Pet. App. 119a. The majority's rationale for this "importation" is that if the patent litigation "is neither a sham nor otherwise baseless, the patent holder is seeking . . . to protect that to which it is presumably entitled" – referring to the presumption of validity, 35 U.S.C. § 282. Pet. App. 43a & n.22.

But "[t]he presumption, like all legal presumptions, is a procedural device, not substantive law." *In re Etter*, 756 F.2d 852, 856 (Fed. Cir. 1985) (citation omitted). A statute setting rules of procedure and assigning burdens to litigants does not "acquire an independent evidentiary role in any proceeding." *Id.* Thus, a patent does not confer a legal right certain. Rather, it reflects an initial judgment by the Patent and Trademark Office – made after only cursory scrutiny – that an invention is patentable. When a patent is asserted in litigation, accused infringers need not prove that it was acquired by fraud or show that it was a "sham" in order to rebut the presumption of validity; they need only demonstrate that the patent should not have been issued. Virtually every accused infringer asserts invalidity, and nearly half of all litigated patents are ultimately found invalid. *See* John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 29 Am. Intell. Prop. L. Ass'n, Q.J. 185 (1998) (studying all patent litigation over an 8 year period and finding that 46% of all patents litigated to judgment were held invalid).

The Second Circuit's ruling essentially allows the patent holder, through the payment of huge sums to alleged infringers, to convert the *rebuttable* (and often rebutted) presumption of patent validity into, for all practical purposes, an *irrebuttable* presumption. The majority thus gave the presumption of validity

improper substantive force, especially where, as here, the presumption *had been rebutted* at the time of the Agreements. The ramifications are especially dire for Hatch-Waxman patent litigation, where generic manufacturers other than the first ANDA-IV filer are likely to be years behind in product development and less financially motivated. *See § III.D. infra.*

Nothing in patent law justifies the resulting safe harbor for weak and defective patents. If instead of fraud or "sham," all that should be required is that the patent be defective, then even if the finding of invalidity that existed at the time of settlement is not dispositive, Plaintiffs should have their own opportunity to show the weaknesses of the patent and the unreasonable restraint of trade resulting from the challenged Agreements. As the dissent points out,

> Both the majority opinion in *Standard Oil* and the concurrence in *Singer* suggest that an antitrust court must go beyond deciding that a lawsuit was not a sham, that is objectively baseless, before it can dismiss an antitrust challenge to the lawsuit's settlement—as opposed to the initiation of the lawsuit—and, in fact, must consider the strength of the patent.

Pet. App. 120a (citing *Standard Oil Co. v. United States*, 283 U.S. 163, 180 (1931); *Singer Mfg. Co.*, 374 U.S. at 197 (White, J. concurring)).

B. The Antitrust Laws Prohibit Unreasonable Restraints of Trade, Including Those That Make Economic Sense for the Participants.

The Second Circuit inexplicably rejected Plaintiffs' antitrust claims largely because it can "make economic sense" to both the patent holder to make, and the generic challenger to accept, a large "reverse payment" to stay out of the market. Pet. App. 44a & n.24. But price-fixing agreements and other conduct prohibited by antitrust laws almost always "make

economic sense" to the participants. The antitrust laws are not designed to protect market participants from doing foolish things that are against their *own* interests. Instead, they prohibit conduct that is in *the participants'* economic self-interest, but that is contrary to the *public's* rightful interest in a competitive market. This aspect of the majority opinion misapprehends a basic point of antitrust economics: price-fixing agreements and other anticompetitive schemes can increase profits to *all* participants because they are at the expense *of the purchasers*, who foot an increased bill which the wrongdoers divide among themselves. *See also* FTC July 2006 Statement, p. 11-12

> "[I]t typically will be more profitable for both parties if the brand-name manufacturer pays the generic manufacturer to settle the patent dispute and agree to defer entry. Although both the brand-name company and the generic company are better off with the settlement, consumers lose the possibility of an earlier generic entry, either because the generic company would have prevailed in the lawsuit or the parties would have negotiated a settlement with an earlier entry date but no payment. Instead, consumers are left with the guarantee of delayed generic entry and paying higher prices."

The Second Circuit's legal basis for inferring lawfulness from mutual profitability is unclear. Perhaps it was drawn from law concerning the "plus factor" of common motive, which holds that conspiracy may be inferred from consciously parallel conduct when, in the absence of a conspiracy, the challenged conduct would present "risk of a substantial loss of" business or goodwill, but "with it there was the prospect of increased profits." *Interstate Circuit, Inc. v. United States*, 306 U.S. 208, 222 (1939). This is referred to as the doctrine of "action against self-interest." *See* VI Phillip E. Areeda, *Antitrust Law*, ¶ 1434c at 243-44 (1986). But it would make a train wreck of antitrust law to hold that conduct that is in the conspiring parties' interests

when an agreement among them exists is not "suspicious" (Pet. App. 42a-43a) and is therefore lawful. The most naked price-fixing would be not "suspicious," and ergo would be lawful, under that ill-conceived legal standard.

C. The Second Circuit Gave Defendants the Benefit of Forced Inferences

The majority tendentiously transmutes plain proof of patent weakness – the patent having being held invalid at the time of the Agreements – into the happy bromide that the patent holder "had sufficient confidence in its patent to proceed to trial." Pet. App. 35a, 47a. But other than settlements entailing large sacrifices of revenue, the patent holder had no viable *alternative* to a trial. Meanwhile, as the dissent points out, the majority finds later victories in defending the patent to be issue-preclusive, even while irreconcilably claiming to honor the longstanding antitrust rule that a challenged agreement must be evaluated based on facts existing when it was made. Pet. App. 34a, n.17, 130a-131a.

Indeed, the Second Circuit's standard would insulate patent holders from antitrust liability in virtually every circumstance. The outcome of trial can only be a win or a loss and the patent holder is protected by both, *i.e.* the patent is either valid, or invalid despite the patent holders "confidence" in going to trial. Notwithstanding the effect of such circular reasoning in this case, the consequences of the Second Circuit's decision are more problematic when weak patents are at stake, since the holders of such patents (who may not have the "confidence" to go to trial) are free to spend monopoly rents on lucrative payments that, economically speaking, cannot rationally be refused by generic competitors. The challenger may receive more money than would have been the case had its challenge succeeded, while the patent holder continues to enjoy monopoly profits, albeit in reduced amounts. The only ones to suffer are the purchasers of the drug. *See* FTC July 2006 Statement, p. 11-12.

D. The Second Circuit Misconstrued the Hatch-Waxman Act and the Incentives It Provides to Generic Firms.

A distressing aspect of the Second Circuit's decision is its assumption that later suits by other patent challengers will be a panacea for anticompetitive effects of "reverse payment" agreements. *See* Pet. App. 50a ("The point will come when there are simply no monopoly profits with which to pay the new generic challengers."). The Second Circuit's (and district court's) contention that settlement with the first ANDA-IV filer simply "clears the field" – implying that a more willing challenger will immediately assume the challenge – defies reality. As the dissent aptly observes, "[t]his position ignores the time gap between" a "reverse payment" settlement and the resolution of such subsequent generic challenges. Pet. App. 121a, n.35.

> A firm must file an ANDA-IV to be eligible for a settlement. The ANDA-IV contains a demonstration by the generic firm that its proposed product is bioequivalent to the innovator's drug, and the firm is capable of making the proposed product. The challenge process requires a detailed description of the basis for belief of invalidity or noninfringement for each of the relevant patents of the innovator. To be a credible threat to the innovator, a generic firm must undertake theses expenses (one generic firm cannot free-ride on another's showing of bioequivalence) and be prepared to see the suit to a conclusion. The number of firms capable of such action is limited.

Hemphill, 81 N.Y.U. L. Rev. at 1582 (footnotes omitted).

The Second Circuit also misconstrued the purpose and effect of the 180 day Exclusivity Period to the first generic manufacturer who challenges the pioneer manufacturer's patent. 21 U.S.C. § 355(j)(5)(B)(iv). The Exclusivity Period is extremely profitable, as it allows the generic manufacturer to

charge supracompetitive prices (only slightly less than the brand). This "head start" also gives the first filer an advantage over subsequent ANDA filers in securing long-term contracts with customers that extend beyond the Exclusivity Period.

> Generic firms other than the first filer will be behind in the approval process, if they have bothered to file at all; they will also be less motivated to initiate or vigorously pursue the challenge. The subsequent filers' return on a challenge, aside from being smaller, depends upon the outcome of the first filers' suit (and possible settlement), providing a strategic motivation to go slow until the uncertainty is reduced. It is therefore inaccurate to assert, as some cases have, that "[i]n a reverse payment case, the settlement leaves the competitive situation unchanged from before the defendant tried to enter the market." The settlement does secure an important change in the competitive situation; it removes from consideration the most motivated challenger, and the one closest to introducing competition. Similarly, although it may be correct in a literal sense that a settlement "clear[s] the field," the implication is very different from that drawn by the Second Circuit [in *Tamoxifen*]: the most vigorous challenger has been removed from the field, thereby removing an important source of early competition.

Hemphill, 81 N.Y.U. L. Rev. at 1586 (footnotes omitted).

Thus, buying off the first ANDA-IV filer could protect the monopoly from any threat of competition for years even if it is premised on a "fatally weak" patent. In the years that may be necessary for subsequent generic challengers to take their position on the "cleared field," holders of weak or defective patents will continue to extract unjustified billions from consumers before the "money runs out" or "reverse payments"

cease. *See* Hovenkamp, § 7.4 at 7-37.[16] The point is analogous to John Maynard Keynes's retort to free market theorists, who argued that an uncontrolled market will correct imbalances "in the long run." "*Long run* is a misleading guide to current affairs. *In the long run* we are all dead." *Bartlett's Familiar Quotations* (16th ed. 1992), p. 652 (emphasis in original; quoting *A Tract on Monetary Reform* [1923], ch. 3).

In addition, as recognized by commentators, the Second Circuit did not appreciate the anticompetitive implications, especially with respect to the legally erroneous suggestion that a generic manufacturer *other* than the first ANDA-IV filer to challenge the innovator's patent could be eligible for the 180 day Exclusivity Period. *See* Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 2046 p. 491 (Supp. 2006).

> [T]he panel majority relied upon the erroneous view that bounty [*i.e.*, 180 day Exclusivity Period] eligibility *does* cede to other [subsequent] filers. According to the majority, the innovator's settlement with the first filer, by neutralizing the competitive threat of the first filer, "opened the [relevant] patent to immediate challenge by other potential generic manufacturers, which did indeed follow – spurred by the additional incentive (at the time) of potentially securing the 180 day exclusivity period available upon a victory in a subsequent infringement action." The majority apparently believed that, at least during the period of the FDA's successful defense interpretation (that is what the panel means by "at the time"), exclusivity eligibility ceded to a later filer.

Hemphill, 81 N.Y.U. L. Rev. at 1584-85 (footnote omitted; emphasis in original). The Second Circuit clearly did not have

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16. As the dissent recognized, "[a]nother generic manufacturer will have to wait at least thirty months after the litigation is commenced against it to begin production." Pet. App. 123a.

"a correct understanding of the exclusivity period [, which] is necessary to a proper understanding of generic firm incentives." *Id.* at 1585.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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APPENDIX

APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT FILED AUGUST 10, 2006

UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

August Term, 2003

(Argued: July 12, 2004. Decided: November 2, 2005

As amended: August 10, 2006)

Docket No. 03-7641

In Re: Tamoxifen Citrate Antitrust Litigation

JOBLOVE, ALLIED SERVS., DIV WELFARE FUND, BENNISH, KOONAN, GREAT LAKES HEALTH PLAN INC., LACAVA, DONEGA, SMITH, LOVINGER, WOOLLACOTT, WHITESIDE, PLATT, UNDERWOOD, TEAMSTERS LOCAL 237, LYNCH, CALLAWAY, MALONEY, MECHANICAL CONTRACT, IBEW-NECA LOCAL 505 HEALTH & WELFARE PLAN, A.F. OF L.-A.G.C. BUILDING TRADES WELFARE FUND, SHEET METAL WORKERS LOCAL 441 HEALTH & WELFARE PLAN, LOCAL 1199 NAT'L BENEFIT FUND FOR HEALTH & HUMAN SERVICES, NEW YORK STATEWIDE SENIOR ACTION COUNCIL, MARKS, BLONSTEIN,

Plaintiffs-Appellants,

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- v -

BARR LABS. INC., ASTRAZENECA PHARMACEUTICALS LP, ZENECA INC., ASTRAZENECA PLC,

Defendants-Appellees.

Before: POOLER, SACK, and RAGGI, *Circuit Judges.* Pooler, Circuit Judge, dissents in a separate opinion.

SACK, *Circuit Judge.*

This appeal, arising out of circumstances surrounding a lawsuit in which a drug manufacturer alleged that its patent for the drug tamoxifen citrate ("tamoxifen") was about to be infringed, and the suit's subsequent settlement, requires us to address issues at the intersection of intellectual property law and antitrust law. Although the particular factual circumstances of this case are unlikely to recur, the issues presented have been much litigated and appear to retain their vitality.

The plaintiffs appeal from a judgment of the United States District Court for the Eastern District of New York (I. Leo Glasser, *Judge*) dismissing their complaint pursuant to Federal Rule of Civil Procedure 12(b)(6). The plaintiffs claim that the defendants conspired, under an agreement settling a patent infringement lawsuit among the defendants in 1993 while an appeal in that lawsuit was pending, to monopolize the market for tamoxifen-the most widely prescribed drug for the treatment of breast cancer-by suppressing competition from generic versions of the drug.

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The settlement agreement included, among other things, a so-called "reverse payment" of $21 million from the defendant patent-holders Zeneca, Inc., AstraZeneca Pharmaceuticals LP, and AstraZeneca PLC (collectively "Zeneca") to the defendant generic manufacturer Barr Laboratories, Inc. ("Barr"), and a license from Zeneca to Barr allowing Barr to sell an unbranded version of Zeneca-manufactured tamoxifen. The settlement agreement was contingent on obtaining a *vacatur* of the judgment of the district court that had heard the infringement action holding the patent to be invalid.

The district court in the instant case concluded that the settlement did not restrain trade in violation of the antitrust laws, and that the plaintiffs suffered no antitrust injury from that settlement. Because we conclude that we have jurisdiction to hear the appeal and that the behavior of the defendants alleged in the complaint would not violate antitrust law, we affirm the judgment of the district court.

REGULATORY BACKGROUND

Before setting forth the salient facts of this case and addressing the merits of the plaintiffs' appeal, it may be helpful to outline the relevant regulatory background.[1]

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1. A similar description of the relevant statutes and regulations is set forth in the Eleventh Circuit's opinion in *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1296-98 (11th Cir.2003), *cert. denied*, 125 S.Ct. 308 (2004), and the District of Columbia Circuit's opinion in *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 801-02 (D.C.Cir.2001), *cert. denied*, 535 U.S. 931, 122 S.Ct. 1305, 152 L.Ed.2d 216 (2002).

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The Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938) (codified at scattered sections of title 21 of the United States Code), prohibits the introduction or delivery for introduction into interstate commerce of "any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of [21 U.S.C. § 355] is effective with respect to such drug." 21 U.S.C. § 355(a). Subsection (b) describes the process of filing a New Drug Application ("NDA") with the United States Food and Drug Administration ("FDA"), which is typically a costly and time-consuming procedure in which the applicant attempts to establish the safety and effectiveness of the drug. *Id.* § 355(b). In 1984, in order to accelerate the approval process for low-cost generic versions of established drugs, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), Pub.L. No. 98-417, 98 Stat. 1585 (codified at scattered sections of titles 21 and 35 of the United States Code). Among other things, the Act added subsection (j) to section 355. Hatch-Waxman Act § 101. Subsection (j) provides for an Abbreviated New Drug Application ("ANDA") to the FDA for the bioequivalent form of a drug already approved for safety and effectiveness. 21 U.S.C. § 355(j)(1), (j)(2)(A), (j)(7)(A). Subsection (j)(7)(A) further provides that the Secretary of the FDA will create and maintain a list of such approved drugs. *Id.* § 355(j)(7)(A). This list, *Approved Drug Products with Therapeutic Equivalence Evaluations*, is commonly known as the "Orange Book."[2] *See id.;* http://www.fda.gov/cder/orange/default.htm.

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2. The ANDA process was intended to be available to manufacturers of generic versions of approved drugs. "A generic (Cont'd)

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An ANDA filer must certify, with respect to each patent that claims the listed drug for the bioequivalent of which the ANDA filer is seeking approval,[3] either that no patent was filed for the listed drug (a "paragraph I" certification), that the patent has expired (a "paragraph II" certification), that the patent will expire on a specified date and the ANDA filer will not market the drug until that date (a "paragraph III" certification), or that the patent is invalid or would not be infringed by the manufacture, use, or sale of the new drug (a "paragraph IV" certification). 21 U.S.C. § 355(j)(2)(A)(vii).

(Cont'd)
version . . . contains the same active ingredients, but not necessarily the same inactive ingredients, as the pioneer drug. A generic drug, as the name implies, is ordinarily sold without a brand name and at a lower price." *Andrx Pharms.*, 256 F.3d at 801 n. 1. Filing an ANDA allows a generic drug manufacturer to avoid the costly and time-consuming process of demonstrating safety and efficacy, allowing the manufacturer to rely on the FDA's earlier findings concerning the brand-name drug's NDA, and thereby facilitates quicker market entry by generic manufacturers. *See id.* at 801.

3. The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.

21 U.S.C. § 355(b)(1).

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An ANDA filer that elects a paragraph IV certification must notify each affected patent owner of the certification. *Id.* § 355(j)(2)(B)(i). The patent owner then has forty-five days after the date it receives such notice to bring suit against the ANDA filer for patent infringement. *Id.* § 355(j)(5)(B)(iii). If no patent owner brings such a lawsuit during this period, the FDA may immediately approve the ANDA. *Id.* If, however, the patent owner brings suit during this period, the FDA's final approval of the ANDA is stayed for thirty months after the date the patent owner received the requisite notice or until a district court[4] returns a decision as to the validity of the patent or its infringement if it does so before the thirty-month period expires. *Id.*

Any approval letter sent by the FDA before the expiration of the prescribed stay and before a court ruling of patent invalidity or non-infringement is tentative. *See* 21 C.F.R. § 314.105(d). If before the thirty months expire a court rules that the patent is either invalid or not infringed, the tentative approval of the ANDA is made effective as of the

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4. At the time of the settlement in this case, the statute did not specify that a district court decision would end the 30-month stay, and the FDA interpreted the statute to require a court decision "from which no appeal can be or has been taken." Ctr. for Drug Evaluation & Research (CDER), Food & Drug Admin., U.S. Dep't of Health & Human Servs., *Guidance for Industry: Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act* 2 (Mar.2000) (quoting 21 C.F.R. § 314.107(e)(1) (1999)) (hereinafter CDER, *Court Decisions*), *available at* http:// www.fda.gov/cder/guidance/3659fnl.pdf (last visited May 12, 2005). In 2000, the FDA changed its interpretation to include any district court decision. *See id.* at 3-5.

date of judgment. 21 U.S.C. § 355(j)(5)(B)(iii)(I). If after thirty months there has been no ruling on patent validity or infringement and the stay expires, the ANDA filer can distribute and market the drug but, depending on the court's later patent ruling, an ANDA filer that chooses to follow this course may thereafter become liable for infringement damages if infringement is found. *See In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 166 F.Supp.2d 740, 744 (E.D.N.Y.2001) ("*Cipro I*").

As an incentive for generic manufacturers to choose the paragraph IV certification route and, in the course of pursuing such applications, to challenge weak patents, the Hatch-Waxman Act offers the first ANDA filer with a paragraph IV certification, under certain conditions, the opportunity to market its generic drug exclusively for 180 days. To this end, the FDA may not approve the ANDA of a subsequent filer until 180 days after the earlier of the date (1) the first ANDA filer commercially markets the generic drug or (2) a court of competent jurisdiction concludes that the patent in question is invalid or not infringed.[5] 21 U.S.C. § 355(j)(5)(B)(iv)(I)-(II).

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5. Like its interpretation of the type of court decision sufficient to end the 30-month stay of final FDA approval described above, at the time of the settlement in this case and until 2000, the FDA interpreted a court decision required to trigger the 180-day period to mean only a court decision "from which no appeal can be or has been taken." *See* CDER, *Court Decisions*, *supra*, at 2 (quoting 21 C.F.R. § 314.107(e)(1) (1999)). That interpretation was subsequently changed in 2000, when the FDA concluded that a patent invalidity decision by a district court would be sufficient to trigger the commencement of the 180-day period. *See id.* at 3-5.

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Until 1998 (and, therefore, at the time of the settlement that is the subject of this appeal), the 180-day exclusivity period was available to the first ANDA filer to elect a paragraph IV certification, but only if the ANDA filer successfully defended against a lawsuit for infringement of the relevant patent. *See* 21 C.F.R. § 314.107(c)(1) (1995). This so-called "successful defense" requirement was challenged in 1997 in two separate lawsuits. In each, the circuit court rejected the requirement as inconsistent with the Hatch-Waxman Act. *See Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1076 (D.C.Cir.1998); *Granutec, Inc. v. Shalala*, 139 F.3d 889, 1998 WL 153410, at *7 (4th Cir. Apr.3, 1998), 1998 U.S.App. LEXIS 6685, at *19-*21 (unpublished opinion).

In June 1998, in response to these decisions, the FDA published a "Guidance for Industry." *See* Ctr. for Drug Evaluation & Research, Food & Drug Admin., U.S. Dep't of Health and Human Servs., *Guidance for Industry: 180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act* (June 1998), *available at* http:// www.fda.gov/cder/guidance/2576fnl.pdf (last visited May 12, 2005). In the "Guidance," the FDA expressed its intention to remove the "successful defense" requirement formally through rulemaking and made clear that thereafter even ANDA paragraph IV filers that are not the subject of lawsuits will be eligible for the 180-day exclusivity period. *Id.* at 4-5. "Until such time as the rulemaking process [was] complete, FDA . . . regulate[d] directly from the statute, and . . . ma[de] decisions on 180-day generic drug exclusivity on a case-by-case basis." *Id.* at 4. Later that year, the FDA formally revoked the

"successful defense" requirement. *See* Effective Date of Approval of an Abbreviated New Drug Application, 63 Fed.Reg. 59,710, 59,710 (Nov. 5, 1998), 21 C.F.R. § 314.107 (1999).

FACTUAL AND PROCEDURAL BACKGROUND

Tamoxifen, the patent for which was obtained by Imperial Chemical Industries, PLC, ("ICI") on August 20, 1985, is sold by Zeneca (a former subsidiary of ICI which succeeded to the ownership rights of the tamoxifen patent) under the trade name Nolvadex®.[6] Tamoxifen is the most widely prescribed drug for the treatment of breast cancer. Indeed, it is the most prescribed cancer drug in the world. In December 1985, four months after ICI was awarded the patent, Barr filed an ANDA with the FDA requesting the agency's approval for Barr to market a generic version of tamoxifen that it had developed. Barr amended its ANDA in September 1987 to include a paragraph IV certification.

In response, on November 2, 1987-within the required forty-five days of Barr's amendment of its ANDA to include a paragraph IV certification-ICI filed a patent infringement lawsuit against Barr and Barr's raw material supplier, Heumann Pharma GmbH & Co. ("Heumann"), in the United States District Court for the Southern District of New York.[7]

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6. In 2001, Zeneca's domestic sales of tamoxifen amounted to $442 million.

7. Soon thereafter, Heumann was dismissed as a defendant after it agreed to be bound by a determination in that case as to the validity of the tamoxifen patent. Compl. ¶ 40.

See Imperial Chem. Indus., PLC v. Barr Labs., Inc., 126 F.R.D. 467, 469 (S.D.N.Y.1989). On April 20, 1992, the district court (Vincent L. Broderick, *Judge*) declared ICI's tamoxifen patent invalid based on the court's conclusion that ICI had deliberately withheld "crucial information" from the Patent and Trademark Office regarding tests that it had conducted on laboratory animals with respect to the safety and effectiveness of the drug. *See Imperial Chem. Indus., PLC v. Barr Labs., Inc.*, 795 F.Supp. 619, 626-27 (S.D.N.Y.1992) (" *Tamoxifen I* "). Those tests had revealed hormonal effects "opposite to those sought in humans," which, the court found, could have "unpredictable and at times disastrous consequences." *Id.* at 622.

ICI appealed the district court's judgment to the United States Court of Appeals for the Federal Circuit. In 1993, while the appeal was pending, the parties entered into a confidential settlement agreement (the "Settlement Agreement") which is the principal subject of this appeal. In the Settlement Agreement, Zeneca (which had succeeded to the ownership rights of the patent) and Barr agreed that in return for $21 million and a non-exclusive license to sell Zeneca-manufactured tamoxifen in the United States under Barr's label, rather than Zeneca's trademark Nolvadex®, Barr would change its ANDA paragraph IV certification to a paragraph III certification, thereby agreeing that it would not market its own generic version of tamoxifen until Zeneca's patent expired in 2002. *See In re Tamoxifen Citrate Antitrust Litig.*, 277 F.Supp.2d 121, 125-26 (E.D.N.Y.2003) (*"Tamoxifen II"*). Zeneca also agreed to pay Heumann $9.5 million immediately, and an additional $35.9 million over the following ten years. The parties further agreed that if the

tamoxifen patent were to be subsequently declared invalid or unenforceable in a final and (in contrast to the district court judgment in *Tamoxifen I*) unappealable judgment by a court of competent jurisdiction, Barr would be allowed to revert to a paragraph IV ANDA certification. Thus if, in another lawsuit, a generic marketer prevailed as Barr had prevailed in *Tamoxifen I*, and that judgment was either not appealed or was affirmed on appeal, Barr would have been allowed to place itself in the same position (but for the 180-day head start, if it was available) that it would have been in had it prevailed on appeal in *Tamoxifen I*, rather than settling while its appeal was pending in the Federal Circuit.

The plaintiffs allege that as a part of the Settlement Agreement, Barr "understood" that if another generic manufacturer attempted to market a version of tamoxifen, Barr would seek to prevent the manufacturer from doing so by attempting to invoke the 180-day exclusivity right possessed by the first "paragraph IV" filer. Compl. ¶ 58. According to the plaintiffs, this understanding among the defendants effectively forestalled the introduction of any generic version of tamoxifen, because, five years later-only a few weeks before other generic manufacturers were to be able to begin marketing their own versions of tamoxifen-Barr did in fact successfully claim entitlement to the exclusivity period. It thereby prevented those manufacturers from entering the tamoxifen market until 180 days after Barr triggered the period by commercially marketing its own generic version of the drug. In fact, Barr had not yet begun marketing its own generic version and had little incentive to do so because, pursuant to the Settlement Agreement, it was already able to market Zeneca's version of tamoxifen.

Meanwhile, pursuant to the Settlement Agreement which was contingent on the *vacatur* of the district court judgment in *Tamoxifen I*, Barr and Zeneca filed a "Joint Motion to Dismiss the Appeal as Moot and to Vacate the Judgment Below." *See Tamoxifen II*, 277 F.Supp.2d at 125. The Federal Circuit granted the motion, thereby vacating the district court's judgment that the patent was invalid. *See Imperial Chem. Indus., PLC v. Heumann Pharma GmbH & Co.*, 991 F.2d 811, 1993 WL 118931, at *1, U.S. App. LEXIS 14872, at *1-*2 (Fed.Cir. Mar. 19, 1993) (unpublished opinion). Such a *vacatur*, while generally considered valid as a matter of appellate procedure by courts at the time of the Settlement Agreement, *see U.S. Philips Corp. v. Windmere Corp.*, 971 F.2d 728, 731 (Fed.Cir.1992), was shortly thereafter held to be invalid in nearly all circumstances by the Supreme Court, *see U.S. Bancorp Mortgage Co. v. Bonner Mall P'ship*, 513 U.S. 18, 27-29, 115 S.Ct. 386, 130 L.Ed.2d 233 (1994).[8]

In the years after the parties entered into the Settlement Agreement and the Federal Circuit vacated the district court's judgment,[9] three other generic manufacturers filed ANDAs

8. The rule in *U.S. Bancorp* does not apply retroactively. *See U.S. Philips Corp. v. Sears Roebuck & Co.*, 55 F.3d 592, 598 (Fed.Cir.), *cert. denied*, 516 U.S. 1010, 116 S.Ct. 567, 133 L.Ed.2d 492 (1995).

9. After the Settlement Agreement was entered into and the *vacatur* ordered, Barr began to market its licensed version of Zeneca's tamoxifen, selling its product to distributors and wholesalers at a 15 percent discount to the brand-name price, which translated into a price to consumers about five percent below Zeneca's otherwise identical Nolvadex® brand-name version. Barr soon captured about 80 percent of the tamoxifen market.

with paragraph IV certifications to secure approval of their respective generic versions of tamoxifen: Novopharm Ltd., in June 1994, Mylan Pharmaceuticals, Inc., in January 1996, and Pharmachemie, B.V., in February 1996.[10] *See Tamoxifen II*, 277 F.Supp.2d at 126-27. Zeneca responded to each of these certifications in the same manner that it had responded to Barr's: by filing a patent infringement lawsuit within the forty-five day time limit provided by 21 U.S.C. § 355(j)(5)(B)(iii). *See id.* In each case, the court rejected the generic manufacturer's attempt to rely on the vacated *Tamoxifen I* decision, and-contrary to the *Tamoxifen I* judgment-upheld the validity of Zeneca's tamoxifen patent. *See Zeneca Ltd. v. Novopharm Ltd.*, 111 F.3d 144, 1997 WL 168318, at *2-*4 (Fed.Cir. Apr.10, 1997), 1997 U.S.App. LEXIS 6634, at *4-*11 (unpublished opinion) (affirming the judgment of the United States District Court for the District of Maryland declining to give *Tamoxifen I* collateral estoppel effect or to apply *U.S. Bancorp* retroactively and deciding that Zeneca's patent was valid); *Zeneca Ltd. v. Pharmachemie B.V.*, 2000 WL 34335805, at *15, 2000 U.S. Dist LEXIS 22631, at *51-*53 (D.Mass. Sept.11, 2000) (concluding that Zeneca had not engaged in inequitable conduct and that the patent was valid); *AstraZeneca UK Ltd. v. Mylan Pharms., Inc.*, No. 00-2239, slip op. at 2-3 (W.D.Pa. Nov. 30, 2000) (entering stipulated consent order that FDA approval for Mylan would not be effective before the expiration of the tamoxifen patent).

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10. Pharmachemie initially filed a paragraph III certification in August 1994, but later amended it to include a paragraph IV certification. *See Tamoxifen II*, 277 F.Supp.2d at 126.

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While Mylan and Pharmachemie's lawsuits were pending in district court, the FDA's "successful defense" rule, requiring that a generic manufacturer seeking to market an allegedly patented drug "successfully defend" its patent infringement lawsuit in order to receive the 180-day exclusivity period-which at the time the Settlement Agreement was entered into would have excluded Barr from benefitting from the exclusivity period-was, as noted, held invalid. *See Mova Pharm. Corp. v. Shalala*, 955 F.Supp. 128, 130-32 (D.D.C.1997), *aff'd in part and rev'd in part on other grounds*, 140 F.3d 1060 (D.C.Cir.1998); *Granutec, Inc. v. Shalala*, 139 F.3d 889, 1998 WL 153410, at *7 (4th Cir. Apr.3, 1998), 1998 U.S.App. LEXIS 6685, at *19-*21 (unpublished opinion). In June 1998, at the time the FDA removed the requirement, Barr-armed with the new rule rendering the first ANDA paragraph IV filer eligible for the 180-day exclusivity period even if it had not successfully defended a patent infringement suit-attempted to block final FDA approval of other generic versions of tamoxifen by claiming entitlement to the 180-day exclusivity period. *See Tamoxifen II*, 277 F.Supp.2d at 127 (citing "Petition for Stay of Action" filed with the FDA on June 26, 1998).

At the time, Pharmachemie had received tentative approval from the FDA to distribute its version of the drug, Mylan was awaiting approval to do the same, and both Pharmachemie and Mylan's thirty-month stays under section 355(j)(5)(B)(iii), triggered by Zeneca's infringement lawsuits, were soon to expire. *See* Compl. ¶¶ 61-63 (noting that the 30-month stay for Mylan was scheduled to expire on July 10, 1998, and for Pharmachemie in August 1998); *Pharmachemie B.V. v. Barr Labs., Inc.*, 276 F.3d 627, 630

(D.C.Cir.2002) (noting that Pharmachemie was granted tentative approval on April 3, 1997); *Mylan Pharms. Inc. v. Henney*, 94 F.Supp.2d 36, 44 (D.D.C.2000), *vacated and dismissed as moot sub nom. Pharmachemie B.V. v. Barr Labs., Inc.*, 284 F.3d 125 (D.C.Cir.2002) (per curiam). Because of the rule change, however, the FDA was able to, and on March 2, 1999, did, grant Barr's petition to confirm its entitlement to the exclusivity period despite the fact that it had settled, rather than "successfully defended" against, Zeneca's lawsuit. *See Tamoxifen II*, 277 F.Supp.2d at 127. The FDA's action effectively delayed the marketing of other generic versions of tamoxifen unless and until Barr triggered and exhausted its 180-day exclusivity period by selling its own generic form of the drug, rather than the version manufactured by Zeneca. As noted, Barr had little incentive to do so because it was already distributing Zeneca's version of tamoxifen.

Pharmachemie and Mylan challenged the FDA's decision. On March 31, 2000, in *Mylan Pharmaceuticals*, the United States District Court for the District of Columbia ruled in Pharmachemie's and Mylan's favor. 94 F.Supp.2d at 54. It concluded that, although Judge Broderick's ruling of invalidity in *Tamoxifen I* had been vacated by the Settlement Agreement, that ruling was still a court decision sufficient to trigger Barr's 180-day exclusivity period, which therefore had already expired. *See Mylan Pharms.*, 94 F.Supp.2d at 54. As a result, on June 26, 2000, the FDA revoked Barr's claim to the 180-day exclusivity period. *See Tamoxifen II*, 277 F.Supp.2d at 127.

On appeal, however, the District of Columbia Circuit vacated the district court's decision as moot. *Pharmachemie*, 276 F.3d at 634; *Pharmachemie*, 284 F.3d at 125. The court noted that subsequent to the FDA's decision to approve Barr's application, the district court had ruled against Pharmachemie in Zeneca's patent infringement lawsuit against it. *See Pharmachemie*, 276 F.3d at 629. Thus, even if, as the district court held in *Mylan*, Barr's 180-day exclusivity period had run, Pharmachemie and Mylan[11] were prohibited by the judgments against them in the patent litigation from marketing their generic versions of tamoxifen until Zeneca's patent expired. Zeneca's patent on tamoxifen expired on August 20, 2002, and generic manufacturers began marketing their own versions of tamoxifen soon thereafter.

Proceedings in the District Court

While these generic manufacturers were litigating the validity of Zeneca's patent on tamoxifen, consumers and consumer groups in various parts of the United States filed some thirty lawsuits challenging the legality of the 1993 Settlement Agreement between Zeneca and Barr. *See Tamoxifen II*, 277 F.Supp.2d at 127. Those lawsuits were subsequently transferred by the Judicial Panel on Multidistrict Litigation to the United States District Court for the Eastern District of New York. Subsequently, a consolidated class action complaint embodying the claims was filed. *In re Tamoxifen Citrate Antitrust Litig.*, 196 F.Supp.2d 1371 (2001); *Tamoxifen II*, 277 F.Supp.2d at 127.

11. Mylan had agreed to follow the *Pharmachemie* court decision. *See Tamoxifen II*, 277 F.Supp.2d at 127; *AstraZemeca UK Ltd.*, No. 00-2239, slip op. at 2-3.

Appendix A

In the consolidated lawsuit, the plaintiffs alleged that the Settlement Agreement unlawfully (1) enabled Zeneca and Barr to resuscitate a patent that the district court had already held to be invalid and unenforceable; (2) facilitated Zeneca's continuing monopolization of the market for tamoxifen; (3) provided for the sharing of unlawful monopoly profits between Zeneca and Barr; (4) maintained an artificially high price for tamoxifen; and (5) prevented competition from other generic manufacturers of tamoxifen. *See Tamoxifen II*, 277 F.Supp.2d at 127-28. At the heart of the lawsuit was the contention that the Settlement Agreement enabled Zeneca and Barr effectively to circumvent the district court's invalidation of Zeneca's tamoxifen patent in *Tamoxifen I*, which, the plaintiffs asserted, would have been affirmed by the Federal Circuit. The result of such an affirmance, according to the plaintiffs, would have been that Barr would have received approval to market a generic version of tamoxifen; Barr would have begun marketing tamoxifen, thereby triggering the 180-day exclusivity period; other generic manufacturers would have introduced their own versions of tamoxifen upon the expiration of the exclusivity period, with Zeneca collaterally estopped from invoking its invalidated patent as a defense; and, as a result, the price for tamoxifen would have declined substantially below the levels at which the Zeneca-manufactured drug in fact sold in the market shared by Zeneca and Barr through the Settlement Agreement. *Id.* at 128. The defendants moved to dismiss the class action complaint pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief can be granted.

Appendix A

On May 15, 2003, in a thorough and thoughtful opinion, the district court granted the defendants' motion to dismiss. *See id.* at 140. The court noted that although market-division agreements between a monopolist and a potential competitor ordinarily violate the Sherman Act, they are not necessarily unlawful when the monopolist is a patent holder. *Id.* at 128-29. Pursuant to a patent grant, the court reasoned, a patent holder may settle patent litigation by entering into a licensing agreement with the alleged infringer without running afoul of the Sherman Act. *Id.* at 129. Yet, the court continued, a patent holder is prohibited from acting in bad faith "beyond the limits of the patent monopoly" to restrain or monopolize trade. *Id.* (quoting *United States v. Line Material Co.*, 333 U.S. 287, 308, 68 S.Ct. 550, 92 L.Ed. 701 (1948) (internal quotation marks omitted)).

Analyzing the terms and impact of the Settlement Agreement, the district court concluded that the agreement permissibly terminated the litigation between the defendants, which "cleared the field for other generic manufacturers to challenge the patent." *Id.* at 133. "Instead of leaving in place an additional barrier to subsequent ANDA filers, the Settlement Agreement in fact removed one possible barrier to final FDA approval-namely, the existence of ongoing litigation between an existing ANDA filer and a subsequent filer." *Id.* To the court, this factor distinguished the case from similar cases in which other circuits had held settlement agreements to be unlawful, where the agreement in question did not conclude the underlying litigation and instead prolonged the period during which other generic manufacturers could not enter the market. *Id.* (distinguishing the Settlement Agreement from the agreements addressed in

In re Terazosin Hydrochloride Antitrust Litig., 164 F.Supp.2d 1340, 1346-47 (S.D.Fla.2000), *rev'd sub nom. Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir.2003), *cert. denied*, 125 S.Ct. 308 (2004), and *In re Cardizem CD Antitrust Litig.*, 105 F.Supp.2d 618, 632 (E.D.Mich.2000), *aff'd*, 332 F.3d 896 (6th Cir.2003), *cert. denied sub nom. Andrx Pharms., Inc. v. Kroger Co.*, 543 U.S. 939, 125 S.Ct. 307, 160 L.Ed.2d 248 (2004)).

The district court was also of the view that the defendants could not be held liable for Barr's FDA petition to preserve its 180-day exclusivity period even if this was a term of the defendants' negotiated Settlement Agreement. *Id.* at 135. It reasoned that at the time of settlement, Barr could not have successfully pursued its FDA application because the FDA continued to apply the "successful defense" rule until 1997. *Id.* at 134. It was only after 1997 that Barr petitioned the FDA to preserve its exclusivity period. The court concluded that Barr's petition was

> an attempt to petition a governmental body in order to protect an arguable interest in a statutory right based on recent developments in the court and at the FDA. As such, the FDA Petition was protected activity under the First Amendment, and long-settled law established that the Sherman Act, with limited exceptions, does not apply to petitioning administrative agencies.

Id. at 135. The court concluded that the plaintiffs' complaint therefore did not sufficiently allege a bad-faith settlement in violation of the Sherman Act. *Id.* at 136.

The district court also concluded that even if the plaintiffs had stated an antitrust violation, they did not suffer antitrust injury from either Barr's exclusivity period or the Settlement Agreement and the resulting *vacatur* of the district court's judgment in *Tamoxifen I* invalidating the tamoxifen patent. *Id.* at 136-38. The court noted that "[a]ntitrust injury ··· must be caused by something other than the regulatory action limiting entry to the market." *Id.* at 137. The court attributed "the lack of competition in the market" not to "the deployment of Barr's exclusivity period, but rather [to] the inability of the generic companies to invalidate or design around" the tamoxifen patent, and their consequent loss of the patent litigation against Zeneca. *Id.* This was so, the district court concluded, even if Barr's petition to the FDA had delayed the approval of Mylan's ANDA. *Id.* at 137. Any "injury" suffered by the plaintiffs, said the court, "is thus not antitrust injury, but rather the result of the legal monopoly that a patent holder possesses." *Id.* at 138.

The district court also rejected the plaintiffs' contention that "the settlement and *vacatur* deprived other generic manufacturers of the ability to make the legal argument that the [*Tamoxifen I*] judgment (if affirmed) would collaterally estop Zeneca from claiming the [tamoxifen] patent was valid in future patent litigation with other ANDA filers." *Id.* It reasoned that there is no basis for the assertion that "forcing other generic manufacturers to litigate the validity of the [tamoxifen] patent[ ] is an injury to competition." *Id.* The court also referred to the other generic manufacturers' subsequent litigation against Zeneca over the validity of the tamoxifen patent, in which Zeneca prevailed, as additional reason to reject the plaintiffs' assertion that the Federal

Circuit would have affirmed Judge Broderick's judgment invalidating the tamoxifen patent. *Id.*

The district court therefore dismissed the plaintiffs' Sherman Act claims. *Id.* It also dismissed the plaintiffs' state-law claims, which had alleged violations of the antitrust laws of seventeen states and violations of consumer protection and unfair competition laws of twenty-one states, because those claims were based on the same allegations as the plaintiffs' federal antitrust claims. *Id.* at 138-40. The plaintiffs appeal the dismissal of their claims.

On July 28, 2003, the defendants moved in this Court to transfer the appeal to the Federal Circuit on the ground that that court alone has jurisdiction to entertain this appeal. For the reasons stated below, we deny the defendants' motion and affirm the district court's judgment dismissing the plaintiffs' complaint.

DISCUSSION

I. Jurisdiction

The defendants argue that this Court does not have jurisdiction to hear this appeal because the case arises under federal patent law and the Federal Circuit has exclusive appellate jurisdiction over such appeals. The plaintiffs respond that we, rather than the Federal Circuit, have appellate jurisdiction because this case does not, on the basis of their well-pleaded complaint, substantially turn on issues of federal patent law. We agree with the plaintiffs.

Appendix A

The United States Court of Appeals for the Federal Circuit has exclusive jurisdiction over an appeal from a federal district court "if the jurisdiction of that court was based, in whole or in part, on section 1338 of [title 28]," with exceptions not pertinent here. 28 U.S.C. § 1295(a)(1). Section 1338, in turn, provides that federal district courts shall have original and exclusive jurisdiction "of any civil action arising under any Act of Congress relating to patents." *Id.* § 1338(a). Therefore, whether the Federal Circuit has jurisdiction over the instant case "turns on whether this is a case 'arising under' a federal patent statute." *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 807, 108 S.Ct. 2166, 100 L.Ed.2d 811 (1988).

A case "arises under" federal patent law if "a well-pleaded complaint establishes either that federal patent law creates the cause of action or that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal patent law, in that patent law is a necessary element of one of the well-pleaded claims." *Id.* at 809, 108 S.Ct. 2166.[12] This is determined "from what necessarily appears in the plaintiff's statement of his own claim in the bill or declaration, unaided by anything alleged in anticipation or

12. The *Christianson* Court employed the "well-pleaded complaint" test that is routinely applied to determine whether a federal district court has federal-question jurisdiction. *See Christianson*, 486 U.S. at 808, 108 S.Ct. 2166 (quoting *Franchise Tax Bd. v. Constr. Laborers Vacation Trust*, 463 U.S. 1, 27-28, 103 S.Ct. 2841, 77 L.Ed.2d 420 (1983)); *see also, e.g., Aetna Health Inc. v. Davila*, 542 U.S. 200, 124 S.Ct. 2488, 2494, 159 L.Ed.2d 312 (2004); *Empire HealthChoice Assurance, Inc. v. McVeigh*, 396 F.3d 136, 140 (2d Cir.2005); *Bracey v. Bd. of Educ.*, 368 F.3d 108, 113 (2d Cir.2004).

avoidance of defenses which it is thought the defendant may interpose." *Id.* (internal quotation marks and citation omitted). "[A] case raising a federal patent-law defense does not, for that reason alone, arise under patent law, even if the defense is anticipated in the plaintiff's complaint, and even if both parties admit that the defense is the only question truly at issue in the case." *Id.* (internal quotation marks and citation omitted).

Moreover, even if one theory supporting a claim essentially turns on an issue arising under patent law, as long as there is at least one alternative theory supporting the claim that does not rely on patent law, there is no "arising under" jurisdiction under 28 U.S.C. § 1338. In that case, as the Supreme Court concluded in *Christianson:* "Since there are reasons completely unrelated to the provisions and purposes of federal patent law why petitioners may or may not be entitled to the relief they seek under their monopolization claim, the claim does not arise under federal patent law." *Id.* at 812, 108 S.Ct. 2166 (internal quotation marks, citation, and alterations omitted); *see also id.* at 810, 108 S.Ct. 2166 ("[A] claim supported by alternative theories in the complaint may not form the basis for § 1338(a) jurisdiction unless patent law is essential to each of those theories.").

Applying these principles to the case at hand, we conclude that we have jurisdiction to entertain this appeal. As we explain below, the defendants' contention that "all of [p]laintiffs' claims arise under the patent law because each requires [p]laintiffs to establish that the [tamoxifen] patent was invalid or unenforceable," Appellees' Reply Mem. Supp. Mot. to Transfer Appeal at 2, is mistaken. The theories that

would enable the plaintiffs to prevail do not require us to examine whether Judge Broderick's invalidation of the tamoxifen patent would have been upheld on appeal or whether the tamoxifen patent was otherwise enforceable and infringed.

If the plaintiffs alleged facts that, if proved, would establish that the Settlement Agreement provided the defendants with benefits exceeding the scope of the tamoxifen patent, they would succeed in alleging an antitrust violation. And if the plaintiffs plausibly alleged that the defendants entered into an agreement to manipulate the 180-day exclusivity period to the defendants' joint benefit, and if they were able to prove based on the facts alleged that they suffered antitrust injury as a result of that agreement, then that, too, would likely be sufficient to state an antitrust violation. Were they to allege and then prove facts sufficient to support either of these theories, the argument that the Settlement Agreement was unlawful "[e]ven if the [tamoxifen p]atent is presumed valid and enforceable," Compl. ¶ 55, would, in our view, be persuasive.

Because we conclude that there are "reasons completely unrelated to the provisions and purposes of the patent laws why the plaintiff[s] may or may not be entitled to the relief [they] seek[ ]," *Christianson*, 486 U.S. at 810, 108 S.Ct. 2166 (internal quotation marks, citation, and alterations omitted), we have jurisdiction to entertain this appeal.

Appendix A

II. Standard of Review

We review a decision on a motion to dismiss *de novo*. *Gregory v. Daly*, 243 F.3d 687, 691 (2d Cir.2001).

"A pleading which sets forth a claim for relief . . . shall contain . . . a short and plain statement of the claim showing that the pleader is entitled to relief." Fed.R.Civ.P. 8(a)(2). "Given the Federal Rules' simplified standard for pleading, a court may dismiss a complaint only if it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations." *Swierkiewicz v. Sorema N.A.*, 534 U.S. 506, 514, 122 S.Ct. 992, 152 L.Ed.2d 1 (2002) (internal quotation marks, citation, and alteration omitted). There is no heightened pleading requirement in antitrust cases. *See Twombly v. Bell Atl. Corp.*, 425 F.3d 99, 108-13 (2d Cir.2005).

In reviewing a decision on a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), we "must accept as true all the factual allegations in the complaint," *Leatherman v. Tarrant County Narcotics Intelligence & Coordination Unit*, 507 U.S. 163, 164, 113 S.Ct. 1160, 122 L.Ed.2d 517 (1993), and "draw all reasonable inferences in plaintiffs' favor," *Freedom Holdings Inc. v. Spitzer*, 357 F.3d 205, 216 (2d Cir.2004). To survive a motion to dismiss, a plaintiff bringing suit under section 1 of the Sherman Act need not allege facts that exclude the possibility that the behavior of which complaint is made is legal. *See Twombly*, 425 F.3d at 111 ("[S]hort of the extremes of 'bare bones' and 'implausibility,' a complaint in an antitrust case need only contain the 'short and plain statement of the claim

showing that the pleader is entitled to relief' that Rule 8(a) requires." (citation omitted)). However, "bald assertions and conclusions of law are not adequate [to state a claim] and a complaint consisting only of naked assertions, and setting forth no facts upon which a court could find a violation of the [law], fails to state a claim under Rule 12(b)(6)." *Gregory*, 243 F.3d at 692 (internal quotation marks and citations omitted). And "[i]t is . . . improper to assume that the plaintiff can prove facts that it has not alleged or that the defendants have violated the antitrust laws in ways that have not been alleged." *Todd v. Exxon Corp.*, 275 F.3d 191, 198 (2d Cir.2001) (internal quotation marks, citation, and alterations omitted). At the same time, in antitrust cases, "plaintiffs should be given the full benefit of their proof without tightly compartmentalizing the various factual components and wiping the slate clean after scrutiny of each." *Cont'l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 699, 82 S.Ct. 1404, 8 L.Ed.2d 777 (1962).

III. The Plaintiffs' Antitrust Claims

A. The Tension between Antitrust Law and Patent Law

With the ultimate goal of stimulating competition and innovation, the Sherman Act prohibits "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States,"[13]

13. "Although the Sherman Act, by its terms, prohibits every agreement 'in restraint of trade,' th[e Supreme] Court has long recognized that Congress intended to outlaw only unreasonable restraints." *State Oil Co. v. Khan*, 522 U.S. 3, 10, 118 S.Ct. 275, 139

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15 U.S.C. § 1, and "monopoliz[ation], or attempt[s] to monopolize, or combin[ations] or conspir[acies] . . . to monopolize any part of the trade or commerce among the several States," *id.* § 2.[14] By contrast, also with the ultimate

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L.Ed.2d 199 (1997). Conduct may be deemed an unreasonable restraint of trade in two ways. Conduct may be considered *per se* unreasonable because it has "such predictable and pernicious anticompetitive effect, and such limited potential for procompetitive benefit." *Id.*

In most cases, however, conduct will be evaluated under a "rule of reason" analysis, "according to which the finder of fact must decide whether the questioned practice imposes an unreasonable restraint on competition, taking into account a variety of factors, including specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint's history, nature, and effect." *Id.* (citation omitted).

The rule-of-reason analysis has been divided into three steps. First, a plaintiff must demonstrate "that the challenged action has had an *actual* adverse effect on competition as a whole in the relevant market." *Capital Imaging Assocs., P.C. v. Mohawk Valley Med. Assocs.*, 996 F.2d 537, 543 (2d Cir.) (emphasis in original), *cert. denied*, 510 U.S. 947, 114 S.Ct. 388, 126 L.Ed.2d 337 (1993). If the plaintiff succeeds in doing so, "the burden shifts to the defendant to establish the 'pro-competitive "redeeming virtues"' of the action." *K.M.B. Warehouse Distribs., Inc. v. Walker Mfg. Co.*, 61 F.3d 123, 127 (2d Cir.1995) (quoting *Capital Imaging Assocs.*, 996 F.2d at 543). If the defendant succeeds in meeting its burden, the plaintiff then has the burden of "show[ing] that the same pro-competitive effect could be achieved through an alternative means that is less restrictive of competition." *Id.*

14. "The offense of monopoly under § 2 of the Sherman Act has two elements: (1) the possession of monopoly power in the (Cont'd)

goal of stimulating competition and innovation, patent law grants an innovator "the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States" for a limited term of years. 35 U.S.C. § 154(a)(1)-(2); *see also Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215, 100 S.Ct. 2601, 65 L.Ed.2d 696 (1980) ("[T]he essence of a patent grant is the right to exclude others from profiting by the patented invention."). It is the tension between restraints on anti-competitive behavior imposed by the Sherman Act and grants of patent monopolies under the patent laws, as complicated by the Hatch-Waxman Act, that underlies this appeal. *See, e.g., United States v. Singer Mfg. Co.*, 374 U.S. 174, 196-97, 83 S.Ct. 1773, 10 L.Ed.2d 823 (1963) ("[T]he possession of a valid patent . . . does not give the patentee any exemption from the provisions of the Sherman Act beyond the limits of the patent monopoly.") (internal quotation marks and citation omitted); *cf. Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 802 (D.C.Cir.2001) ("Although the Congress was interested in increasing the availability of generic drugs, it also wanted to protect the patent rights of the pioneer applicants."), *cert. denied*, 535 U.S. 931, 122 S.Ct. 1305, 152 L.Ed.2d 216 (2002); *Schering-Plough Corp. v. F.T.C.*, 402 F.3d 1056, 1067 (11th Cir.2005) ("Although the exclusionary power of a patent may seem incongruous with the goals of antitrust law,

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relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71, 86 S.Ct. 1698, 16 L.Ed.2d 778 (1966).

a delicate balance must be drawn between the two regulatory schemes.").

B. The Plaintiffs' Allegations

1. Settlement of a Patent Validity Lawsuit. The plaintiffs contend that several factors-including that *Tamoxifen I* was settled after the tamoxifen patent had been held invalid by the district court, making the patent unenforceable at the time of settlement-indicate that if their allegations are proved, the defendants violated the antitrust laws. They argue that the district court in the case before us erred by treating the tamoxifen patent as valid and enforceable. Instead, they say, in accordance with the never-reviewed judgment in *Tamoxifen I*, the district court in this case should have treated the patent as presumptively invalid for purposes of assaying the sufficiency of the plaintiffs' complaint.

We begin our analysis against the backdrop of our longstanding adherence to the principle that "courts are bound to encourage" the settlement of litigation. *Gambale v. Deutsche Bank AG*, 377 F.3d 133, 143 (2d Cir.2004). "Where a case is complex and expensive, and resolution of the case will benefit the public, the public has a strong interest in settlement. The trial court must protect the public interest, as well as the interests of the parties, by encouraging the most fair and efficient resolution." *United States v. Glens Falls Newspapers, Inc.*, 160 F.3d 853, 856-57 (2d Cir.1998). As the Eleventh Circuit recently noted in drug patent litigation similar to the one before us, "There is no question that settlements provide a number of private and social

benefits as opposed to the inveterate and costly effects of litigation." *Schering-Plough*, 402 F.3d at 1075.

It is well settled that "[w]here there are legitimately conflicting [patent] claims . . . , a settlement by agreement, rather than litigation, is not precluded by the [Sherman] Act," although such a settlement may ultimately have an adverse effect on competition. *Standard Oil Co. v. United States*, 283 U.S. 163, 171, 51 S.Ct. 421, 75 L.Ed. 926 (1931); *cf. Flex-Foot, Inc. v. CRP, Inc.*, 238 F.3d 1362, 1369 (Fed.Cir.2001) ("[W]hile the federal patent laws favor full and free competition in the use of ideas in the public domain over the technical requirements of contract doctrine, settlement of litigation is more strongly favored by the law."); *Nestle Co. v. Chester's Mkt., Inc.*, 756 F.2d 280, 284 (2d Cir.1985) ("[T]he district court imposed the heavy burden on trademark defendants of having to continue to litigate when they would prefer to settle, a ruling without precedent."), *overruled on other grounds, U.S. Bancorp Mortgage Co. v. Bonner Mall P'ship*, 513 U.S. 18, 27-29, 115 S.Ct. 386, 130 L.Ed.2d 233 (1994); *Duplan Corp. v. Deering Milliken, Inc.*, 540 F.2d 1215, 1220 (4th Cir.1976) ("[T]he settlement of patent litigation, in and of itself, does not violate the antitrust laws."); *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F.Supp.2d 986, 991 (N.D.Ill.2003) (Posner, J., sitting by designation) ("The general policy of the law is to favor the settlement of litigation, and the policy extends to the settlement of patent infringement suits.").

Rules severely restricting patent settlements might also be contrary to the goals of the patent laws because the increased number of continuing lawsuits that would result

would heighten the uncertainty surrounding patents and might delay innovation. *See Valley Drug*, 344 F.3d at 1308; Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 Fla. L.Rev. 747, 749 (2002). Although forcing patent litigation to continue might benefit consumers in some instances, "patent settlements can . . . promote efficiencies, resolving disputes that might otherwise block or delay the market entry of valuable inventions." Joseph F. Brodley & Maureen A. O'Rourke, *Preliminary Views: Patent Settlement Agreements*, Antitrust, Summer 2002, at 53.[15] As the Fourth Circuit has observed, "It is only when settlement agreements are entered into in bad faith and are utilized as part of a scheme to restrain

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15. It is true that had the defendants not settled the underlying patent litigation and had the district court's judgment been affirmed on appeal, Zeneca would have been estopped from asserting the validity of its patent against others seeking to enter the market. *See Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 350, 91 S.Ct. 1434, 28 L.Ed.2d 788 (1971). However, it is clearly a permissible byproduct of settlement that future hypothetical plaintiffs might be forced to relitigate the same issues involved in the settled case. Furthermore, before 1994, when district court judgments were vacated as a matter of course upon settlement, *see U.S. Bancorp*, 513 U.S. at 29, 115 S.Ct. 386 (virtually ending this practice), there was similarly and permissibly no collateral estoppel effect accorded these judgments for the benefit of future hypothetical plaintiffs. *See Nestle*, 756 F.2d at 284 ("Drumbeating about the need to protect other unknown users of the trademark [in question] will ring hollow indeed in the ears of the present defendants if the peril of a reversal is realized. . . . We see no justification to force these defendants, who wish only to settle the present litigation, to act as unwilling private attorneys general and to bear the various costs and risks of litigation.").

or monopolize trade that antitrust violations may occur." *Duplan Corp.*, 540 F.2d at 1220.

We cannot judge this post-trial, pre-appeal settlement on the basis of the likelihood *vel non* of Zeneca's success had it not settled but rather pursued its appeal. As the Supreme Court noted in another context, "[i]t is just not possible for a litigant to prove in advance that the judicial system will lead to any particular result in his case." *Whitmore v. Arkansas*, 495 U.S. 149, 159-60, 110 S.Ct. 1717, 109 L.Ed.2d 135 (1990). Similarly, "[n]o one can be *certain* that he will prevail in a patent suit." *Asahi Glass*, 289 F.Supp.2d at 993 (emphasis in original). We cannot guess with any degree of assurance what the Federal Circuit would have done on an appeal from the district court's judgment in *Tamoxifen I*. *Cf. In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F.Supp.2d 188, 200-01 (E.D.N.Y.2003) ("*Cipro II*") (noting that courts should not speculate about the outcome of litigation) (citing *Boehm v. Comm'r*, 146 F.2d 553 (2d Cir.), *aff'd*, 326 U.S. 287, 66 S.Ct. 120, 90 L.Ed. 78 (1945)); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F.Supp.2d 514, 529 (E.D.N.Y.2005) ("*Cipro III*") ("[M]aking the legality of a patent settlement agreement, on pain of treble damages, contingent on a later court's assessment of the patent's validity might chill patent settlements altogether."). And because in this case any such guess is retrospective, it would in any event be of limited value in assessing the behavior of the defendants at the relevant time: when they were entering into the Settlement Agreement. *See Valley Drug*, 344 F.3d at 1306 ("[T]he reasonableness of agreements under the antitrust laws are to be judged at the time the agreements are entered into.") (citing, *inter alia*, *SCM Corp.*

v. Xerox Corp., 645 F.2d 1195, 1207 (2d Cir.1981), *cert. denied*, 455 U.S. 1016, 102 S.Ct. 1708, 72 L.Ed.2d 132 (1982)).

As the plaintiffs correctly point out, the Federal Circuit would have reviewed Judge Broderick's factual findings underlying his conclusion of invalidity with considerable deference, rather than engaging in a presumption of validity. *See Shelcore, Inc. v. Durham Indus., Inc.*, 745 F.2d 621, 624-25 (Fed.Cir.1984) ("The presumption of validity does not guide our analysis on appeal. Rather, we review the findings and conclusions of a district court under the appropriate standards of review."). But it takes no citation to authority to conclude that appellants prevail with some frequency in federal courts of appeals even when a high degree of deference is accorded the district courts from which the appeals are taken.[16] Accordingly, it does not follow from the deference that was due by the Federal Circuit to the district court in *Tamoxifen I* that Zeneca would have been unsuccessful on appeal. *See Cipro III*, 363 F.Supp.2d at 529 (noting that with few exceptions "courts assessing the legality of patent settlement agreements have not engaged in a *post hoc* determination of the potential validity of the underlying patent . . . when deciding whether an agreement concerning the patent violates antitrust law").

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16. It may be worth noting, although in and of itself it seems to us to prove little, that the Federal Circuit reversed district court determinations of patent invalidity at a relatively high rate during the relevant time period. *See* Donald R. Dunner *et al.*, *A Statistical Look at the Federal Circuit's Patent Decisions: 1982-1994*, 5 Fed. Cir. B.J. 151, 154-55 (1995).

The facts of this case provide an additional reason for us to embrace the general rule that we will ordinarily refrain from guessing what a court will hold or would have held. As noted earlier, federal district courts in later lawsuits seeking to enforce the tamoxifen patent concluded, contrary to the court in *Tamoxifen I*, that the patent was, in fact, valid. While we do not think that these results enable us to estimate the chances that the Federal Circuit would have reversed the judgment of the district court in *Tamoxifen I*, they at least suggest the extent to which the outcome of such proceedings may be unpredictable.[17]

The fact that the settlement here occurred after the district court ruled against Zeneca seems to us to be of little moment. There is a risk of loss in all appeals that may give rise to a desire on the part of both the appellant and the appellee to settle before the appeal is decided.[18] Settlements of legitimate

17. We thus think that it was appropriate for the district court to take these decisions into account for the limited purpose of rebutting the plaintiffs' conclusory allegation that the Federal Circuit would have affirmed Judge Broderick's decision invalidating the tamoxifen patent. *See Mason v. Am. Tobacco Co.*, 346 F.3d 36, 39 (2d Cir.2003) ("[L]egal conclusions, deductions or opinions couched as factual allegations are not given a presumption of truthfulness." (internal quotation marks and citations omitted)), *cert. denied*, 541 U.S. 1057, 124 S.Ct. 2163, 158 L.Ed.2d 757 (2004); *Smith v. Local 819 I.B.T. Pension Plan*, 291 F.3d 236, 240 (2d Cir.2002) ("[C]onclusory allegations or legal conclusions masquerading as factual conclusions will not suffice to prevent a motion to dismiss." (internal quotation marks and citation omitted)).

18. Indeed, our Circuit requires civil litigants to go through a pre-argument, Court-sponsored process called the Civil Appeals (Cont'd)

disputes, even antitrust and patent disputes of which an appeal is pending, in order to eliminate that risk, are not prohibited. That Zeneca had sufficient confidence in its patent to proceed to trial rather than find some means to settle the case first should hardly weigh against it.

We conclude, then, that without alleging something more than the fact that Zeneca settled after it lost to Barr in the district court that would tend to establish that the Settlement Agreement was unlawful, the assertion that there was a bar-antitrust or otherwise-to the defendants' settling the litigation at the time that they did is unpersuasive.

2. Reverse Payments. Payments pursuant to the settlement of a patent suit such as those required under the Settlement Agreement are referred to as "reverse" payments because, by contrast, "[t]ypically, in patent infringement cases the payment flows from the alleged infringer to the patent holder." David A. Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*, 55 Food & Drug L.J. 321, 335 (2000). Here, the patent holder, which, if its patent is valid, has the right to prevent the alleged infringer from making commercial use of it, nonetheless pays that party not to do so. Seeking to

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Management Plan ("CAMP"), *see http://www.ca2.uscourts.gov/Docs/Forms/CAMP.pdf* and *http://www.ca2.uscourts.gov/Docs/Forms/Preargument.pdf*, designed in part to facilitate just such post-judgment, pre-appellate argument settlements-which it accomplishes with significant success. *See* Gilbert J. Ginsburg, *The Case for a Mediation Program in the Federal Circuit*, 50 Am. U. L.Rev. 1379, 1383 (2001) (reporting estimate that forty-five to fifty percent of civil cases pending before the Second Circuit settle each year).

supply the "something more" than the fact of settlement that would render the Settlement Agreement unlawful, the plaintiffs allege that the value of the reverse payments from Zeneca to Barr thereunder "greatly exceeded the value of Barr's 'best case scenario' in winning the appeal . . . and entering the market with its own generic product." Appellants' Br. at 27.

It is the size, not the mere existence, of Zeneca's reverse payment that the plaintiffs point to in asserting that they have successfully pleaded a Sherman Act cause of action. In explaining our analysis, though, it is worth exploring the notion advanced by others that the very existence of reverse payments establishes unlawfulness. *See* Balto, *supra*, at 335 ("A payment flowing from the innovator to the challenging generic firm may suggest strongly the anticompetitive intent of the parties in entering the agreement and the rent-preserving effect of that agreement."); Herbert Hovenkamp *et al.*, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L.Rev. 1719, 1751 (2003) ("[T]he problem of exclusion payments can arise whenever the patentee has an incentive to postpone determination of the validity of its patent.").

Heeding the advice of several courts and commentators, we decline to conclude (and repeat that the plaintiffs do not ask us to conclude) that reverse payments are *per se* violations of the Sherman Act such that an allegation of an agreement to make reverse payments suffices to assert an antitrust violation. We do not think that the fact that the patent holder is paying to protect its patent monopoly, without more, establishes a Sherman Act violation. *See Valley Drug*, 344

F.3d at 1309 (concluding *390 that the presence of a reverse payment, by itself, does not transform an otherwise lawful settlement into an unlawful one); *Asahi Glass*, 289 F.Supp.2d at 994 (asserting that "[a] ban on reverse-payment settlements would reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought anticompetitive," and observing that if the parties decided not to settle, and the patent holder ultimately prevailed in the infringement lawsuit, there would be the same level of competition as in the reverse payment case); Thomas F. Cotter, *Refining the "Presumptive Illegality" Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis & Lemley*, 87 Minn. L.Rev. 1789, 1807 (2003) (stating that "the plaintiff often will have an incentive to pay the defendant not to enter the market, regardless of whether the former expects to win at trial," which "suggests that reverse payments should not be per se illegal, since they are just as consistent with a high probability of validity and infringement as they are with a low probability. It also suggests that reverse payments should not be per se legal for the same reason."). *But see Cardizem*, 332 F.3d at 911 (calling a forty-million-dollar reverse payment to a generic manufacturer "a naked, horizontal restraint of trade that is *per se* illegal because it is presumed to have the effect of reducing competition in the market for Cardizem CD and its generic equivalents to the detriment of consumers").

As other courts have noted, moreover, reverse payments are particularly to be expected in the drug-patent context because the Hatch-Waxman Act created an environment that encourages them. *See Cipro II*, 261 F.Supp.2d at 252 (noting

that the Hatch-Waxman Act "has the unintended consequence of altering the litigation risks of patent lawsuits" and concluding that "reverse payments are a natural by-product of the Hatch-Waxman process"); *accord Schering-Plough*, 402 F.3d at 1074.

In the typical patent infringement case, the alleged infringer enters the market with its drug after the investment of substantial sums of money for manufacturing, marketing, legal fees, and the like. The patent holder then brings suit against the alleged infringer seeking damages for, *inter alia*, its lost profits. If the patent holder wins, it receives protection for the patent and money damages for the infringement. And in that event, the infringer loses not only the opportunity to continue in the business of making and selling the infringing product, but also the investment it made to enter the market for that product in the first place. And it must pay damages to boot. It makes sense in such a circumstance for the alleged infringer to enter into a settlement in which it pays a significant amount to the patent holder to rid itself of the risk of losing the litigation.

By contrast, under the Hatch-Waxman Act, the patent holder ordinarily brings suit shortly after the paragraph IV ANDA has been filed- *before* the filer has spent substantial sums on the manufacturing, marketing, or distribution of the potentially infringing generic drug. The prospective generic manufacturer therefore has relatively little to lose in litigation precipitated by a paragraph IV certification beyond litigation costs and the opportunity for future profits from selling the generic drug. Conversely, there are no infringement damages for the patent holder to recover, and there is therefore little

reason for it to pursue the litigation beyond the point at which it can assure itself that no infringement will occur in the first place.

Accordingly, a generic marketer has few disincentives to file an ANDA with a paragraph IV certification. The incentive, by contrast, may be immense: the profits it will likely garner in competing with the patent holder without having invested substantially in the development of the drug, and, in addition, possible entitlement to a 180-day period (to be triggered at its inclination) during which it would be the exclusive seller of the generic drug in the market.[19]

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19. In this case, Barr could not at the time of the Settlement Agreement count on obtaining the 180-day exclusive period from the FDA because, as a settler rather than a "successful defender," it at least appeared that it was unlikely to be entitled to the period of exclusivity-in other words, it appeared that, by settling, Barr was trading away its exclusivity period. It is noteworthy, nonetheless, that the 180-day period is of substantial benefit to the generic drug manufacturer who obtains it because it gives that manufacturer a significant head start over other manufacturers. *See, e.g., Geneva Pharms. Tech. Corp. v. Barr Labs. Inc.*, 386 F.3d 485, 494, 510 (2d Cir.2004) (considering claim that defendant's first-mover status converted a transitory advantage into a permanent one, where plaintiffs provided testimony that "even though its offer price to the Eckerd and CVS drugstore chains was as much as 25 percent below [the first mover's price], neither chain was willing to leave [the first mover] after having devoted substantial time to switching patients and getting their pharmacists comfortable with the new product"); *Mova Pharm.*, 955 F.Supp. at 131 ("All parties recognize that the earliest generic drug manufacturer in a specific market has a distinct advantage over later entrants.").

Appendix A

The patent holder's risk if it loses the resulting patent suit is correspondingly large: It will be stripped of its patent monopoly. At the same time, it stands to gain little from winning other than the continued protection of its lawful monopoly over the manufacture and sale of the drug in question.

"Hatch-Waxman essentially redistributes the relative risk assessments and explains the flow of settlement funds and their magnitude. Because of the Hatch-Waxman scheme, [the generic challengers] gain[ ] considerable leverage in patent litigation: the exposure to liability amount[s] to litigation costs, but pale[s] in comparison to the immense volume of generic sales and profits." *Schering-Plough*, 402 F.3d at 1074 (citation omitted).

Under these circumstances, we see no sound basis for categorically condemning reverse payments employed to lift the uncertainty surrounding the validity and scope of the holder's patent.[20]

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20. It has been observed that even the typical settlement of the ordinary patent infringement suit appears to involve what may be characterized as a reverse payment. *See Cipro II*, 261 F.Supp.2d at 252 ("[E]ven in the traditional context, implicit consideration flows from the patent holder to the alleged infringer."); *cf. Asahi Glass*, 289 F.Supp.2d at 994 ("*[A]ny* settlement agreement can be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement. If any settlement agreement is thus to be classified as involving a forbidden 'reverse payment,' we shall have no more patent settlements." (emphasis in original)); Daniel A. Crane, *Ease Over Accuracy in Assessing Patent Settlements*, 88 Minn. L.Rev. 698, 700

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Appendix A

3. "Excessive" Reverse Payments. As we have noted, although there are those who contend that reverse payments are in and of themselves necessarily unlawful, the plaintiffs are not among them. They allege instead that "[t]he value of the consideration provided to keep Barr's product off the market . . . greatly exceeded the value Barr could have realized by successfully defending its trial victory on appeal and entering the market with its own competitive generic product." Appellants' Br. at 15. The plaintiffs assert that it is that excessiveness that renders the Settlement Agreement unlawful.[21] We agree that even if "reverse payments are a natural by-product of the Hatch-Waxman process," *Cipro II*,

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(2004) ("It makes no sense to single out exclusion payments for disfavor when the same potential for collusion arises in any settlement involving the defendant's exit."). A blanket rule that all settlements involving reverse payments are unlawful could thus conceivably endanger many ordinary settlements of patent litigation.

21. The Federal Trade Commission and some commentators have proposed similar or even more stringent rules. *See In re Schering-Plough Corp.*, 2003 WL 22989651 , 2003 FTC LEXIS 187 (Dec. 8, 2003) (applying a rule under which generic manufacturers would not be permitted to receive reverse payments that exceeded "the lesser of the [patent] [h]older's expected future litigation costs to resolve the Patent Infringement Claim or $2 million"), *vacated*, 402 F.3d 1056 (11th Cir.2005); Hovenkamp *et al.*, *supra*, at 1759 (proposing that "[i]n an antitrust challenge, a payment from a patentee to an infringement defendant for the latter's exit from the market is presumptively unlawful," and that the "infringement plaintiff can defend by showing both (1) that the ex ante likelihood of prevailing in its infringement lawsuit is significant, and (2) that the size of the payment is no more than the expected value of litigation and collateral costs attending the lawsuit").

261 F.Supp.2d at 252, it does not follow that they are necessarily lawful, *see* Hovenkamp *et al.*, *supra*, at 1758 ("We do not think it follows that because it is rational for the patentee to agree to an exclusion payment, that payment cannot be anticompetitive. Far from it."). But

> [o]nly if a patent settlement is a device for circumventing antitrust law is it vulnerable to an antitrust suit. Suppose a seller obtains a patent that it knows is almost certainly invalid (that is, almost certain not to survive a judicial challenge), sues its competitors, and settles the suit by licensing them to use its patent in exchange for their agreeing not to sell the patented product for less than the price specified in the license. In such a case, the patent, the suit, and the settlement would be devices-masks-for fixing prices, in violation of antitrust law.

Asahi Glass, 289 F.Supp.2d at 991. "If, however, there is nothing suspicious about the circumstances of a patent settlement, then to prevent a cloud from being cast over the settlement process a third party should not be permitted to haul the parties to the settlement over the hot coals of antitrust litigation." *Id.* at 992.

There is something on the face of it that does seem "suspicious" about a patent holder settling patent litigation against a potential generic manufacturer by paying that manufacturer more than either party anticipates the manufacturer would earn by winning the lawsuit and entering the newly competitive market in competition with the patent

holder. Why, after all-viewing the settlement through an antitrust lens-should the potential competitor be permitted to receive such a windfall at the ultimate expense of drug purchasers? We think, however, that the suspicion abates upon reflection. In such a case, so long as the patent litigation is neither a sham nor otherwise baseless, the patent holder is seeking to arrive at a settlement in order to protect that to which it is presumably entitled: a lawful monopoly over the manufacture and distribution of the patented product.[22]

If the patent holder loses its patent monopoly as a result of defeat in patent litigation against the generic manufacturer, it will likely lose some substantial portion of the market for the drug to that generic manufacturer and perhaps others.

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22. The dissent questions what it sees as our reliance on the presumption of validity of the patent at the time of the settlement. Even after a district court holds a patent invalid, it is treated as presumptively valid under 35 U.S.C. § 282 on appeal. *See Rosco, Inc. v. Mirror Lite Co.*, 304 F.3d 1373, 1377-78 (Fed.Cir.2002). But irrespective of whether there was a presumption or where any such presumption lay at the time of settlement, we think that Zeneca was then entitled to protect its tamoxifen patent monopoly through settlement. The question for this Court is whether the settlement extended the patent's scope. If the judgment of the district court against a patent's validity put an end to the patent monopoly that the patent holder was entitled to protect, then *any* settlement after judgment of the district court holding the patent invalid would extend the patent monopoly beyond the patent's scope and therefore be unlawful. We do not think that to be the law, a view which appears to be consistent with the plaintiffs'. *See* Appellants' Reply Br. at 4, Heading "B." ("Hatch-Waxman Patent Infringement Litigation Can Be Settled, Even On Appeal, Without Violating The Antitrust Laws.").

The patent holder might also (but will not necessarily)[23] lower its price in response to the competition. The result will be, unsurprisingly, that (assuming that lower prices do not attract significant new purchasers for the drug) the *total* profits of the patent holder and the generic manufacturer on the drug in the competitive market will be *lower* than the total profits of the patent holder alone under a patent-conferred monopoly. In the words of the Federal Trade Commission: "The anticipated profits of the patent holder in the absence of generic competition are greater than the sum of its profits and the profits of the generic entrant when the two compete." *In re Schering-Plough Corp.*, 2003 WL 22989651 (Dec. 8, 2003), 2003 FTC LEXIS 187, *vacated*, 402 F.3d 1056 (11th Cir.2005). It might therefore make economic sense for the patent holder to pay some portion of that difference to the generic manufacturer to maintain the patent-monopoly market for itself. And, if that amount exceeds what the generic manufacturer sees as its likely profit from victory, it seems to make obvious economic sense for the generic manufacturer to accept such a payment if it is offered.[24] We think we can

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23. There is authority for the proposition that when its patent monopoly is ended, the patent holder might actually *raise* the price on its branded product, rather than lower it in response to generic competition. *See* Congr. Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* 29-31 (July 1998), *available at* http://www.cbo.gov/ftpdocs/6xx/doc655/pharm.pdf (last visited May 12, 2005).

24. To illustrate using a vastly oversimplified hypothetical example (ignoring, for example, legal fees and costs): Suppose the patent holder is selling 1,000,000 pills per year at a $1 profit per pill

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safely assume that the patent holder will seek to pay less if it can, but under the circumstances of a paragraph IV Hatch-Waxman filing, as we have discussed, the ANDA filer might well have the whip hand. *Cf. Valley Drug*, 344 F.3d at 1310 ("Given the asymmetries of risk and large profits at stake, even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement.").

Of course, the law could provide that the willingness of the patent holder to settle at a price above the generic

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(for a total profit of $1,000,000). The generic manufacturer files a paragraph IV ANDA, and the patent holder responds by bringing suit to protect its patent. If the patent holder projects that, should it lose the suit, it will thereafter sell only 250,000 pills per year at a $.90 profit per pill (for a total profit of $225,000) in the competitive market, and the generic will sell 750,000 pills per year at a profit of $.60 per pill (for a total profit of $450,000)-so that total market profits are now down from $1,000,000 to $675,000-it would make economic sense for the patent holder to pay the generic manufacturer something more than the $450,000 the generic manufacturer would make in a competitive market to settle the litigation. If it paid $500,000 a year to the generic manufacturer-$50,000 more than the generic manufacturer could earn in the market in a "best case scenario"-for example, it would thereby retain the ability to make $500,000 per year selling its branded pills ($1,000,000 profit less $500,000 per year paid to the generic), $275,000 *more* per year than it would earn if it paid nothing to the generic but lost the patent litigation and with it the patent monopoly. It might well be sensible for the patent holder to enter into this sort of settlement, depending in part on its perceived prospects for winning the litigation, and it would seem difficult for the generic manufacturer to refuse. The $325,000 of yearly monopoly profits which accrued to the patent holder before the litigation began would thereafter be divided between the patent holder and the generic manufacturer.

manufacturer's projected profit betrays a fatal disbelief in the validity of the patent or the likelihood of infringement, and that the patent holder therefore ought not to be allowed to maintain its monopoly position. Perhaps it is unwise to protect patent monopolies that rest on such dubious patents. But even if large reverse payments indicate a patent holder's lack of confidence in its patent's strength or breadth, we doubt the wisdom of deeming a patent effectively invalid on the basis of a patent holder's fear of losing it.

> [T]he private thoughts of a patentee, or of the alleged infringer who settles with him, about whether the patent is valid or whether it has been infringed is not the issue in an antitrust case. A firm that has received a patent from the patent office (and not by fraud . . .), and thus enjoys the presumption of validity that attaches to an issued patent, 35 U.S.C. § 282, is entitled to defend the patent's validity in court, to sue alleged infringers, and to settle with them, whatever its private doubts, unless a neutral observer would reasonably think either that the patent was almost certain to be declared invalid, or the defendants were almost certain to be found not to have infringed it, if the suit went to judgment. It is not "bad faith" to assert patent rights that one is not certain will be upheld in a suit for infringement pressed to judgment and to settle the suit to avoid risking the loss of the rights. No one can be *certain* that he will prevail in a patent suit.

Asahi Glass, 289 F.Supp.2d at 992-93 (citation omitted) (emphasis in original).

Such a rule would also fail to give sufficient consideration to the patent holder's incentive to settle the lawsuit without reference to the amount the generic manufacturer might earn in a competitive market, even when it is relatively confident of the validity of its patent-to insure against the possibility that its confidence is misplaced, or, put another way, that a reviewing court might (in its view) render an erroneous decision. *Cf. Schering-Plough*, 402 F.3d at 1075-76. Whatever the degree of the patent holder's certainty, there is always some risk of loss that the patent holder might wish to insure against by settling.

This case is illustrative. It is understandable that however sure Zeneca was at the outset that its patent was valid, settlement might have seemed attractive once it lost in the district court, especially in light of the deferential standard the Federal Circuit was expected to apply on review. But its desire to settle does not necessarily belie Zeneca's confidence in the patent's validity. Indeed, Zeneca's pursuit of subsequent litigation seeking to establish the tamoxifen patent's validity, and the success of that litigation, strongly suggest that such confidence persisted and was not misplaced. Neither do we think that the settlement's entry after the district court rendered a judgment against Zeneca should counsel against the settlement's propriety. It would be odd to handicap the ability of Zeneca to settle after it had displayed sufficient confidence in its patent to risk a finding of invalidity by taking the case to trial.

We are unsure, too, what would be accomplished by a rule that would effectively outlaw payments by patent holders to generic manufacturers greater than what the latter would

be able to earn in the market were they to defend successfully against an infringement claim. A patent holder might well prefer such a settlement limitation-it would make such a settlement cheaper-while a generic manufacturer might nonetheless agree to settle because it is less risky to accept in settlement all the profits it expects to make in a competitive market rather than first to defend and win a lawsuit, and then to enter the marketplace and earn the profits. If such a limitation had been in place here, Zeneca might have saved money by paying Barr the maximum such a rule might allow-what Barr was likely to earn if it entered the market-and Barr would have received less than it could have if it were free to negotiate the best deal available-as it did here. But the resulting level of competition, and its benefit to consumers, would have been the same. The monopoly would have nonetheless endured-but, to no apparent purpose, at less expense to Zeneca and less reward for Barr.

It strikes us, in other words, as pointless to permit parties to enter into an agreement settling the litigation between them, thereby protecting the patent holder's monopoly even though it may be based on a relatively weak patent, but to limit the amount of the settlement to the amount of the generic manufacturer's projected profits had it won the litigation.

We are not unaware of a troubling dynamic that is at work in these cases. The less sound the patent or the less clear the infringement, and therefore the less justified the monopoly enjoyed by the patent holder, the more a rule permitting settlement is likely to benefit the patent holder by allowing it to retain the patent. But the law allows the settlement even of suits involving weak patents with the

presumption that the patent is valid and that settlement is merely an extension of the valid patent monopoly. So long as the law encourages settlement, weak patent cases will likely be settled even though such settlements will inevitably protect patent monopolies that are, perhaps, undeserved.

We also agree with the *Cipro III* court's observation that:

> If courts do not discount the exclusionary power of the patent by the probability of the patent's being held invalid, then the patents most likely to be the subject of exclusion payments would be precisely those patents that have the most questionable validity. This concern, on its face, is quite powerful. But the answer to this concern lies in the fact that, while the strategy of paying off a generic company to drop its patent challenge would work to exclude that particular competitor from the market, it would have no effect on other challengers of the patent, whose incentive to mount a challenge would also grow commensurately with the chance that the patent would be held invalid.

Cipro III, 363 F.Supp.2d at 534. There is, of course, the possibility that the patent holder will continue to buy out potential competition such that a settlement with one generic manufacturer protecting the patent holder's ill-gotten patent monopoly will be followed by other settlements with other generic manufacturers should a second, third, and fourth rise to challenge the patent. We doubt, however, that this scenario is realistic.

Appendix A

Every settlement payment to a generic manufacturer reduces the profitability of the patent monopoly. The point will come when there are simply no monopoly profits with which to pay the new generic challengers. "[I]t is unlikely that the holder of *396 a weak patent could stave off *all* possible challengers with exclusion payments because the economics simply would not justify it." *Cipro III*, 363 F.Supp.2d at 535 (emphasis supplied). We note in this regard that Zeneca settled its first tamoxifen lawsuit against the first generic manufacturer, Barr, but did not settle, and, as far as we know, did not attempt to settle, the litigation it brought against the subsequent challenging generics, Novopharm, Pharmachemie, and Mylan. (To be sure, the settlement with Barr came after a judgment *against* Zeneca, while the judgments in Novopharm, Pharmachemie, and Mylan's challenges were *for* Zeneca.)[25]

An alternative rule is, of course, possible. As suggested above, the antitrust laws could be read to outlaw all, or nearly all, settlements of Hatch-Waxman infringement actions. Patent holders would be required to litigate each threatened patent to final, unappealable judgment. Only patents that the

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25. It seems to us odd for the dissent to urge, in the context of this case, that we have not given proper weight to "the public interest in having the validity of patents litigated." The Settlement Agreement was a virtual invitation to other generic manufacturers to file paragraph IV certifications and thereby court litigation as to the validity of the tamoxifen patent. It was an invitation that was accepted three times leading to three lawsuits, two of them litigated to judgment, as to the validity of the tamoxifen patent. Accepting the value of litigating the validity of patents in these circumstances, it has hardly been undermined here.

courts held were valid would be entitled to confer monopoly power on their proprietors. But such a requirement would be contrary to well-established principles of law. As we have rehearsed at some length above, settlement of patent litigation is not only suffered, it is encouraged for a variety of reasons even if it leads in some cases to the survival of monopolies created by what would otherwise be fatally weak patents. It is too late in the journey for us to alter course.[26]

We generally agree, then, with the Eleventh Circuit insofar as it held in *Valley Drug* that " 'simply because a brand-name pharmaceutical company holding a patent paid its generic competitor money cannot be the sole basis for a violation of antitrust law,' unless the 'exclusionary effects of the agreement' exceed the 'scope of the patent's protection.' " *Cipro III*, 363 F.Supp.2d at 538 (quoting *Schering-Plough*, 402 F.3d at 1076 (alteration omitted)). Whatever damage is done to competition by settlement is done pursuant to the monopoly extended to the patent holder by patent law unless the terms of the settlement enlarge the scope of that monopoly. "Unless and until the patent is shown to have been procured by fraud, or a suit for its enforcement

26. The dissent "see[s] no reason why the general standard for evaluating an anti-competitive agreement, i.e., its reasonableness, should not govern in this context." We think, such a rule, making every settlement of patent litigation, at least in the Hatch-Waxman Act context, subject to the inevitable, lengthy and expensive hindsight of a jury as to whether the settlement constituted a "reasonable" restraint (and, in this case, whether the Federal Circuit would have affirmed or reversed in a patent appeal), would place a huge damper on such settlements contrary to the law that we have discussed at some length that settlements are not only permitted, they are to be encouraged.

is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent." *Cipro III*, 363 F.Supp.2d at 535.

We further agree with the *Cipro III* court that absent an extension of the monopoly beyond the patent's scope, an issue that we address in the next section of this *397 opinion, and absent fraud, which is not alleged here, the question is whether the underlying infringement lawsuit was "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits." *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60, 113 S.Ct. 1920, 123 L.Ed.2d 611 (1993).[27] In this

27. The reasoning of the dissent, which quotes an excerpt from this statement, is, in our view, largely based on a repeated mischaracterization of our views in this regard. We do not, as the dissent states in one form or another many times, think that there is a "requirement" that antitrust plaintiffs "must show that the settled litigation was a sham, i.e., objectively baseless, before the settlement can be considered an antitrust violation . . . ,". There is no such requirement. The central criterion as to the legality of a patent settlement agreement is whether it "exceeds the 'scope of the patent's protection.' " As we pointed out at the outset of this discussion, we think that "[i]f the plaintiffs alleged facts that, if proved, would establish that the Settlement Agreement provided the defendants with benefits exceeding the scope of the tamoxifen patent, they would succeed in alleging an antitrust violation." ("[T]he question is whether the 'exclusionary effects of the agreement' exceed the 'scope of the patent's protection.' *Schering-Plough*, 402 F.3d at 1076."). A plaintiff need not allege or prove sham litigation in order to succeed in establishing that a settlement has provided defendants "with

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case, the plaintiffs do not contend that they can-and we conclude that in all likelihood they cannot-establish that Zeneca's patent litigation was baseless, particularly in light of the subsequent series of decisions upholding the validity of the same patent. *Cf. id.* at 60 n. 5, 113 S.Ct. 1920 ("A winning lawsuit is by definition a reasonable effort at petitioning for redress and therefore not a sham."). Payments, even "excessive" payments, to settle the dispute were therefore not necessarily unlawful.

4. The Terms of the Settlement Agreement. Inasmuch as we conclude that neither the fact of settlement nor the amount of payments made pursuant thereto as alleged by the plaintiffs would render the Settlement Agreement unlawful, we must assess its other terms to determine whether they do. As we have explained in the previous section of this opinion, we think that the question is whether the "exclusionary effects of the agreement" exceed the "scope of the patent's protection." *Schering-Plough*, 402 F.3d at 1076. Looking to other courts that have addressed similar cases for guidance, and accepting the plaintiffs' allegations as true, we conclude that the Settlement Agreement did not unlawfully extend the reach of Zeneca's tamoxifen patent.

First, the Settlement Agreement did not extend the patent monopoly by restraining the introduction or marketing of unrelated or non-infringing products. It is thus unlike the

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benefits exceeding the scope of the tamoxifen patent." Whether there is fraud or baseless litigation may be relevant to the inquiry, but it is hardly, we think, "the . . . standard," as the dissent posits in order to take issue with it.

agreement the Sixth Circuit held *per se* illegal in *Cardizem*, 332 F.3d at 908, which included not only a substantial reverse payment but also an agreement that the generic manufacturer would not market non-infringing products. *See id.* at 902, 908 & n. 13 (quoting the court in *Cipro II*, 261 F.Supp.2d at 242, which observed that the *Cardizem* district court, in condemning the settlement agreement in that case, " 'emphasized that the agreement [there] restrained Andrx from marketing other bioequivalent or generic versions of Cardizem that were not at issue in the pending litigation, ... Thus, the court found that the agreement's restrictions extended to noninfringing and/or potentially noninfringing versions of generic Cardizem.' " (alterations in original)); *see also Valley Drug*, 344 F.3d at 1306 n. 18 (observing that if the agreement "also prohibited the marketing of non-infringing terazosin products, prohibited [the generic manufacturer] from marketing infringing products beyond the date a district court held the [relevant] patent invalid, and prohibited [the generic manufacturer] from waiving its 180-day exclusivity period" then the agreement "may be beyond the scope of [the patent holder's] lawful right to exclude and, if so, would expose appellants to antitrust liability"); *In re K-Dur Antitrust Litig.*, 338 F.Supp.2d 517, 532 (D.N.J.2004) (noting, in connection with a private lawsuit involving the same settlement agreements challenged by the FTC in *Schering-Plough*, that the plaintiffs "alleged that [the generic manufacturer] not only agreed not to enter the market with the allegedly infringing generic drug at issue in the patent litigation, but agreed not to enter the market with *any* generic competitor drug, irrespective of whether it infringed the patent" and that another potential distributor of generic equivalents also agreed to delay marketing a

generic competitor drug and "agreed not to conduct, sponsor, file or support any study of a generic drug's bioequivalence to [the patented drug] before the expiration of the [relevant] patent," and concluding: "These agreements, as alleged, grant rights to Schering in excess of what is granted by the [relevant] patent alone." (emphasis in original)).

Like the patent for the compound ciprofloxacin hydrochloride, which was the subject of dispute in the *Cipro* cases, and unlike the patents at issue in *Cardizem* and *Valley Drug*, Zeneca's tamoxifen patent is not a formulation patent, which covers only specific formulations or delivery methods of compounds; rather, it is a patent on a compound that, by its nature, excludes all generic versions of the drug. *See* Appellees' Br. at 23; *Cipro II*, 261 F.Supp.2d at 249-50 (observing that the patent in that case covered all formulations and the generic manufacturer could not have avoided it). Because Zeneca's patent therefore precludes all generic versions of tamoxifen, so that any such competing version would, as we understand it, necessarily infringe the patent, the Settlement Agreement did not, by precluding the manufacture of a generic version of tamoxifen, restrain the marketing of any non-infringing products.

Second, the Settlement Agreement ended all litigation between Zeneca and Barr and thereby opened the tamoxifen patent to immediate challenge by other potential generic manufacturers, which did indeed follow-spurred by the additional incentive (at the time) of potentially securing the 180-day exclusivity period available upon a victory in a subsequent infringement lawsuit, since by vacating the district court judgment, Barr ensured (under procedures in

effect at the time) that it was not eligible for the exclusivity period. *See Cipro II*, 261 F.Supp.2d at 242-43 (emphasizing that the settlement in that case extinguished the litigation between Barr and Bayer and that Barr thereby relinquished its claim to the 180-day exclusivity period, thus removing any "bottleneck" to future generic entrants). The Agreement thus avoided a "bottleneck" of the type created by the agreements in *Valley Drug* and *Cardizem*, which prevented other generic manufacturers from obtaining approval for their own generic versions from the FDA. Rather than resolve the litigation, the settlements in those cases prolonged it by providing incentives to the defendant generic manufacturers not to pursue the litigation avidly. In *Cardizem*, for example, the settlement included periodic payments to the generic manufacturer during the pendency of the lawsuit in exchange for its promise not to market a generic drug for *399 which it had already received FDA approval, thereby delaying the market entry of other generic manufacturers "who could not enter until the expiration of [the first-moving generic manufacturer's] 180-day period of marketing exclusivity, which [the generic] had agreed not to relinquish or transfer." *Cardizem*, 332 F.3d at 907; *see also Cipro II*, 261 F.Supp.2d at 243 (noting that in *Valley Drug*, the generic manufacturer had obtained final FDA approval, yet the settlement agreement "delayed triggering [the generic manufacturer's] 180-day exclusivity period, effectively holding up FDA approval of other generic manufacturers' ANDA IVs.").

The disadvantage purportedly suffered by the plaintiffs is not that Barr somehow prevented others from challenging the patent and obtaining FDA approval; nor is it that no other generic manufacturer tried to do so. It is instead that each of

the subsequent challenges failed. While it is true that, had the district court's decision in Zeneca's patent infringement lawsuit against Barr been affirmed, other generic manufacturers would have been allowed to market their drugs, there is no legal requirement that parties litigate an issue fully for the benefit of others. *See, e.g., Nestle*, 756 F.2d at 284.

Thus the stated terms of the Settlement Agreement include nothing that would place it beyond the legitimate exclusionary scope of Zeneca's patent: The Settlement Agreement did not have an impact on the marketing of non-infringing or unrelated products, and the Agreement fully resolved the litigation between Zeneca and Barr, clearing the way for other generic manufacturers to seek to enter the market.

Finally, the Settlement Agreement did not entirely foreclose competition in the market for tamoxifen. It included a license from Zeneca to Barr that allowed Barr to begin marketing Zeneca's version of tamoxifen eight months after the Settlement Agreement became effective. The license ensured that money also flowed from Barr to Zeneca, decreasing the value of the reverse payment. By licensing tamoxifen to Barr, Zeneca added a competitor to the market, however limited the competition may have been. Unlike reverse payment settlements that leave the competitive situation as it was prior to the litigation,[28] the reverse payment

28. *See Asahi Glass*, 289 F.Supp.2d at 994 (noting that in the typical reverse-payment case, "the settlement leaves the competitive situation unchanged from before the defendant tried to enter the market.").

in this case was pursuant to an agreement that increased competition in the market for tamoxifen-even if only a little-almost nine years before the tamoxifen patent was to expire. *Cf. Cipro II*, 261 F.Supp.2d at 209 (noting that if the patent holder had not agreed to pay the generic manufacturers "hundreds of millions of dollars," then the patent holder "would have issued to [the generic manufacturers] a license for distribution of generic Cipro").

The Settlement Agreement almost certainly resulted in less price competition than if Barr had introduced its own generic version, of course. The plaintiffs allege that the Barr-distributed, Zeneca-manufactured tamoxifen sold at retail for just five percent less than the Zeneca-branded version, Compl. ¶ 75, compared with what the plaintiffs allege is a typical initial drop of sixteen percent or more, *see* Oral Argument Tr., July 12, 2004, at 5, and an eventual drop in a truly competitive market of thirty to eighty percent, Compl. ¶ 75. *See also* Congr. Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* 32 (July *400 1998), *available at* http://www.cbo.gov/ftpdocs/6xx/doc655/pharm.pdf (last visited May 12, 2005) (describing one study that estimated that the average price of a generic drug fell from sixty percent of the brand-name price to thirty-four percent of the brand-name price as the number of generic manufacturers increased from one to ten). This was competition nonetheless. It was certainly more competition than would have occurred had there been no settlement and had Zeneca prevailed on appeal. *Cf. Nestle*, 756 F.2d at 284 (noting that the district court erred by not placing more weight on the consequences of requiring the litigation to go forward,

such as the fact that "the appellees will be forced to bear the costs and risks of further litigation, including the non-trivial risk of a reversal on the merits").

We conclude that the facts as alleged in the plaintiffs' complaint, if proved, would not establish that the terms of the Settlement Agreement violated the antitrust laws. In the absence of any plausible allegation that the reverse payment provided benefits to Zeneca outside the scope of the tamoxifen patent, the plaintiffs have not stated a claim for relief with respect to the Settlement Agreement. *See Twombly*, 425 F.3d at 111.

5. Barr's 180-Day Exclusivity Period. The plaintiffs also advance allegations regarding actions that Barr took with respect to the 180-day exclusivity period to which the first paragraph IV filer is entitled under the Hatch-Waxman Act. We confess that it is not altogether clear to us what the import of those allegations is. The plaintiffs contend that Barr's attempt to assert its exclusivity period in 1998, five years after the date of the Settlement Agreement, should be viewed as "circumstantial evidence demonstrating the anticompetitive consequences of [the] agreement[ ]" among the defendants. Appellants' Reply Br. at 13. They allege that the Settlement Agreement was drafted "careful[ly] to preserve Barr's" ability to "strategically deploy[ ]" its claim to the exclusivity period. Compl. ¶ 57. And they further allege the existence of an understanding among the defendants as to when and under what circumstances "Barr would assert its claimed exclusivity period rights to prevent . . . FDA approval" of other generic manufacturers' ANDA applications, "even if Zeneca was unsuccessful in using

patent litigation to keep another generic competitor off the market."[29] *Id.* ¶ 58. They also contend that because they have alleged an unlawful conspiracy, the issue is only "whether Barr's conduct in blocking generic entry was in furtherance of that alleged conspiracy." Appellants' Br. at 35 (emphasis omitted).

The defendants contend in response that any consequences of the 180-day exclusivity period resulted from Barr's petition to the FDA, and that Barr's actions in claiming the 180-day exclusivity period were therefore immune from antitrust scrutiny under the *Noerr-Pennington* doctrine, which immunizes parties from antitrust liability for injuries resulting from government action prompted by the parties' petitioning activities. *See E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 136, 81 S.Ct. 523, 5 L.Ed.2d 464 (1961) (stating that "the Sherman Act does not prohibit two or more persons from associating together in an attempt to persuade the legislature or the executive [or an agency or a court] to take particular action with respect to a law that would produce a restraint or a monopoly"); *United Mine Workers of Am. v. Pennington*, 381 U.S. 657, 670, 85 S.Ct. 1585, 14 L.Ed.2d 626 (1965) ("Joint efforts to influence public officials do not violate the antitrust laws even though intended to eliminate competition."). Such immunity does not disappear even if the petitioning activity is intended to harm competitors. *See Noerr*, 365 U.S. at 138-39, 81 S.Ct. 523. In this case, the defendants assert, because Barr's petitioning activity was protected under *Noerr-Pennington*, it cannot be the basis for antitrust liability.

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29. Of course, as it turned out, Zeneca *was* successful in subsequently protecting its patent in the courts.

We are not so sure. Although *Noerr-Pennington* immunity may lend Barr's actions some protection, it does not immunize all actions with respect to the 180-day exclusivity period from antitrust scrutiny. The doctrine does not extend protection to the defendants "where the alleged conspiracy 'is a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor.' " *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 511, 92 S.Ct. 609, 30 L.Ed.2d 642 (1972) (quoting *Noerr*, 365 U.S. at 144, 81 S.Ct. 523). And it "does not authorize anticompetitive *action* in advance of [the] government's adopting the industry's anticompetitive proposal. The doctrine applies when such action is the consequence of legislation or other governmental action, not when it is the means for obtaining such action." *In re Brand Name Prescription Drugs Antitrust Litig.*, 186 F.3d 781, 789 (7th Cir.1999) (emphasis in original); *see also Juster Assocs. v. City of Rutland*, 901 F.2d 266, 271-72 (2d Cir.1990) (stating that when a claimed restraint is the consequence of government action, it falls within the purview of *Noerr-Pennington* immunity, but when the restraint is the means by which the defendants seek to obtain favorable government action, it does not). Because we think that an agreement to time the deployment of the exclusivity period to extend a patent's monopoly power might well constitute anticompetitive action outside the scope of a valid patent, we decline to rest our conclusion on the ground of *Noerr-Pennington* immunity.[30]

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30. "The competitive concern is that the 180-day exclusivity provision can be used strategically by a patent holder to prolong its market power in ways that go beyond the intent of the patent laws

(Cont'd)

We nonetheless do not think that the facts as alleged with respect to Barr's claim to the 180-day exclusivity period amount to an antitrust violation.

First, as we have explained, our review of the Settlement Agreement convinces us that, accepting the plaintiffs' allegations as true, the defendants did not violate the antitrust laws merely by entering into it. Therefore, even if we were to view Barr's actions with regard to the 180-day exclusivity period as somehow constituting "evidence"–"circumstantial" or otherwise-of the "anticompetitive consequences" of the Settlement Agreement, it would not affect our conclusion. The Agreement is no doubt "anticompetitive"-the plaintiffs need no additional proof of that. It limited competition between generic tamoxifen and Zeneca's branded product. But, as we have seen, because it did not exceed the scope of the tamoxifen patent, it was not an *unlawful* anticompetitive agreement.

(Cont'd)

and the Hatch-Waxman Act by delaying generic entry for a substantial period." Balto, *supra*, at 331. An agreement that a "generic manufacturer would not relinquish its 180-day exclusivity . . . prevent[s] other generic manufacturers from entering as well." *Id.* at 335; *see also* Hovenkamp *et al.*, *supra*, at 1755 ("It is widely understood that the 180-day exclusivity period offers the potential for collusive settlement arrangements between pioneers and generics. A pioneer could initiate a patent infringement suit against a first generic ANDA filer and settle the litigation with a 'non-entry' payment to the generic, under which the generic would delay commercialization of the generic product, thus postponing the commencement of the 180-day exclusivity period and locking other generics out of the market indefinitely.").

Second, because we have concluded that the Settlement Agreement was not itself an unlawful conspiracy, Barr's "block[ing of] generic entry" would not be unlawful as "in furtherance of" an unlawful conspiracy. There would have to *be* an unlawful conspiracy before Barr's actions could contribute to it.

Third, [t]he factual predicate that is pleaded does need to include [an unlawful] conspiracy among the realm of plausible possibilities. *Twombly*, 425 F.3d at 111 (footnote omitted). Assuming that the plaintiffs intended to allege a separate agreement among the defendants relating to Barr's manipulation of its exclusivity period in order to protect the defendants from competition from other generic manufacturers, the pleaded conspiracy seems to us to be "implausible."

At the time the Settlement Agreement was entered into, the established law was that a generic manufacturer must "successfully defend" a patent infringement lawsuit in order to obtain exclusivity.[31] Accordingly, even if Barr might have

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31. In *Andrx*, the defendant attempted unsuccessfully to claim that it was unable to cause any delay in generic entry because the "successful defense" requirement would prevent it from doing so. *Andrx Pharms.*, 256 F.3d at 810. The D.C. Circuit noted that the settlement agreement in that case was signed in September 1997-after the district court in *Mova* issued, in January 1997, a preliminary injunction banning the enforcement of the successful defense requirement. *Id.* (citing *Mova Pharm.*, 955 F.Supp. at 131-32). Thus, "[t]he timing of the Agreement and of the demise of the successful defense requirement defeats Andrx's argument on this point." *Id.* In the instant case, however, the Settlement Agreement was executed long before *Mova* struck down the successful defense requirement.

suspected that the FDA would drop its "successful defense" requirement, it had, at the time, no claim to the exclusionary period. Although the Agreement in this case did include a provision allowing Barr to revert its paragraph III certification back to a paragraph IV certification in the event another generic manufacturer successfully invalidated the patent, it seems farfetched, in light of the law at the time, to construe that provision as a conscious and unlawful attempt to manipulate the exclusivity period.

Moreover, the fact that Barr acted as it did with respect to the deployment of the exclusionary period is easily explained by Barr's own interest in protecting itself from competition through a petition to the FDA for a statutorily prescribed benefit. Nothing that we can draw from the facts alleged in the complaint indicates how Barr's actions in this regard suggest that it was in league with Zeneca.[32]

Fourth and last, we have grave doubt as to whether, even if the defendants agreed to deploy the exclusionary period to protect their shared monopoly power, the injury that the defendants allege they suffered in this regard constitutes "antitrust injury."

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32. The dissent says that a reasonable fact-finder might conclude that sophisticated parties would not have included a provision that allowed Barr to re-file under paragraph IV absent an unlawfully anticompetitive purpose because it "had no potential benefit to either of them" apart from an anti-competitive one. We disagree. If another generic manufacturer had been successful in having the tamoxifen patent held invalid, it was strongly and legitimately in Barr's interest to be able to re-file so that it could market tamoxifen without risking a violation of the Settlement Agreement.

Appendix A

To state a claim under the Sherman Act, a plaintiff, in addition to stating an antitrust violation, must allege facts sufficient to prove that it suffered "antitrust injury, which is to say injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful." *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489, 97 S.Ct. 690, 50 L.Ed.2d 701 (1977) (emphasis omitted); *see also George Haug Co., Inc. v. Rolls Royce Motor Cars Inc.*, 148 F.3d 136, 139 (2d Cir.1998). "The injury should reflect the anticompetitive effect either of the violation or of anticompetitive acts made possible by the violation." *Brunswick*, 429 U.S. at 489, 97 S.Ct. 690. "Harm to the antitrust plaintiff is sufficient to satisfy the constitutional standing requirement of injury in fact." *Associated Gen. Contractors, Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 535 n. 31, 103 S.Ct. 897, 74 L.Ed.2d 723 (1983).

Accepting for the sake of argument that the plaintiffs have stated an antitrust violation by alleging an agreement or understanding between Barr and Zeneca to manipulate the 180-day exclusivity period, we are inclined to agree with the district court's conclusion that any injury that the plaintiffs suffered nonetheless resulted from Zeneca's valid patent and from the inability of other generic manufacturers to establish that the patent was either invalid or not infringed-and not from any agreement between Barr and Zeneca that Barr should employ its exclusivity powers to exclude competition. *See Tamoxifen II*, 277 F.Supp.2d at 136-38.

As we have noted, at the time that Zeneca and Barr entered into the Settlement Agreement and caused the district

court's judgment of patent invalidity to be vacated, Barr was not entitled to the 180-day period of exclusivity. It was only after the FDA announced that it was abandoning the "successful defense" requirement that Barr asserted its claim to the exclusivity period. *See Tamoxifen II*, 277 F.Supp.2d at 135. As the district court noted:

> Barr did *not* seek similar relief when Novopharm filed its ANDA and challenged the [tamoxifen] patent between 1994 and 1997. Only after the events in 1997 and 1998 . . . did Barr attempt to assert its rights. If Barr intended to protect its exclusivity period on behalf of itself and Zeneca *pursuant to the Settlement Agreement*, Barr's inactivity during the pendency of the Novopharm litigation is inexplicable.

Id. at 134 n. 9 (emphasis in original).

Therefore, the plaintiffs could not have suffered any antitrust injury with regard to an exclusivity period for Barr from the time the defendants signed the Settlement Agreement until the time the regulations were changed in 1997-1998. During that period, as far as all parties were concerned, the Settlement Agreement had indeed "cleared the field" so that other generic challengers could enter the market. Accordingly, any injury suffered by the plaintiffs during that time period was the result of Zeneca's legitimate patent monopoly-which remained intact as a result of the lawful Settlement Agreement-and not the result of any steps that Barr took.

The plaintiffs also suffered no antitrust injury from the time the "successful defense" requirement was eliminated until, in 2000, the FDA rejected Barr's claim to the exclusivity period, because the other ANDA filers with a paragraph IV certification ultimately lost their infringement suits against Zeneca. Even if Barr had not successfully petitioned the FDA, other generic manufacturers would not have been *404 able to enter the market with their generic versions without infringing the tamoxifen patent. As the district court rightly noted, this allegation of injury is "based on the lack of competition that could have only existed by illegally infringing on the [tamoxifen p]atent." *Id.* at 137-38. Thus, the plaintiffs did not suffer antitrust injury then either. *See, e.g., Axis, S.p.A. v. Micafil, Inc.*, 870 F.2d 1105, 1111 (6th Cir.), *cert. denied*, 493 U.S. 823, 110 S.Ct. 83, 107 L.Ed.2d 49 (1989) (finding no antitrust injury where plaintiffs had stated an antitrust violation, but where the alleged injury would have resulted even in the absence of the antitrust violation, because of the existence of patents preventing market entry).

Finally, there is clearly no antitrust injury with regard to Barr's use of the exclusivity period after the FDA rejected Barr's claim to the exclusivity period in 2000. From that time on, no one could have thought that Barr had a claim to an exclusivity period. Any injury suffered by the plaintiffs arose from Zeneca's patent monopoly, which remained valid until its expiration in 2002, after which other generic manufacturers did, in fact, enter the market.

For the foregoing reasons, we conclude that the plaintiffs have not sufficiently stated an antitrust claim arising out of

the defendants' actions with regard to Barr's 180-day exclusionary period.

IV. Leave To Amend

The plaintiffs contend that the district court erred in not addressing, and therefore in effectively denying, their request to amend their complaint to state a claim on which relief could be granted. The defendants reply that the district court acted within its discretion in effectively denying the plaintiffs' request-which appeared in a footnote in the middle of their brief opposing the defendants' motion to dismiss-because the request was buried and because it was, in any event, futile.

Federal Rule of Civil Procedure 15(a) provides that "a party may amend the party's pleading . . . by leave of court . . . and leave shall be freely given when justice so requires." A district court has broad discretion to decide whether to grant leave to amend, a decision that we review for an abuse of discretion. *Gurary v. Winehouse*, 235 F.3d 792, 801 (2d Cir.2000). It is within the court's discretion to deny leave to amend implicitly by not addressing the request when leave is requested informally in a brief filed in opposition to a motion to dismiss. *See id.* Furthermore, where amendment would be futile, denial of leave to amend is proper. *See Van Buskirk v. N.Y. Times Co.*, 325 F.3d 87, 91-92 (2d Cir.2003).

The plaintiffs' assertion that, if granted leave to amend, they "would be able to redress perceived deficiencies" in their complaint, Appellants' Br. at 56, does not persuade us. Even were plaintiffs to allege-as they now assert they are able to—that the defendants were concerned about the

possibility that the Settlement Agreement might run afoul of antitrust law, or that the reverse payments were in excess of Zeneca's litigation costs but "less than the substantial losses Zeneca anticipated upon generic competition," or that the defendants "believed the Federal Circuit would likely affirm" the invalidation of the tamoxifen patent, *id.*, in the absence of any plausible allegation that Zeneca's patent infringement lawsuit was baseless or that the Settlement Agreement otherwise restrained competition beyond the scope of the tamoxifen patent, their complaint would fail to state a claim on which relief can be granted.

"[I]t appears beyond doubt that the plaintiff[s] can prove no set of facts in support of [their] claim which would entitle [them] to relief." *Conley v. Gibson*, 355 U.S. 41, 45-46, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957). The district court therefore did not abuse its discretion in denying the plaintiffs' request for leave to amend.

CONCLUSION

For the foregoing reasons, the judgment of the district court is affirmed.

APPENDIX B — MEMORANDUM OF THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK FILED MAY 14, 2003

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

MDL. No. 1408 (ILG)

IN RE TAMOXIFEN CITRATE ANTITRUST LITIGATION

MEMORANDUM
MDL No. 1408 (ILG)

GLASSER, District Judge:

SUMMARY

Plaintiffs are eighteen individuals (the "consumer plaintiffs"), eleven organizations (or their trustees) which provide certain medical benefits for their members (the "third-party payor plaintiffs"), and six consumer advocacy groups representing consumer plaintiffs (the "consumer advocacy plaintiffs") (collectively, "Plaintiffs"). Plaintiffs bring this action essentially alleging that defendant Zeneca, Inc. (together with co-defendant Astrazeneca Pharmaceuticals LP, "Zeneca") entered into an agreement with defendant Barr Laboratories, Inc. ("Barr") (collectively, "Defendants") that, while nominally settling an appeal of a judgment that declared the patent for the drug tamoxifen citrate ("tamoxifen") invalid, in fact monopolized and allocated the United States market for tamoxifen. Plaintiffs allege that this agreement violated the laws of the United States and the laws of twenty-

two states. Defendants now move to dismiss the complaint on a variety of grounds. For the reasons states below, their motions are granted.

BACKGROUND

The actions involve the drug tamoxifen, the most essential drug for treatment of breast cancer.[1] Breast cancer is the most common malignancy and is one of the leading causes of death among women. During the 1990's, more than 1.5 million women in the United States were newly diagnosed with breast cancer. Tamoxifen is a synthetic hormone developed in the 1970's that is used, in addition to or in lieu of more drastic forms of therapy, to treat both early and advanced-stage breast cancer and to prevent recurrence. Tamoxifen has become the most widely prescribed treatment for breast cancer, and indeed is the single most-prescribed drug in the world for any cancer. The World Health Organization lists tamoxifen as an "Essential Drug," and tamoxifen is the standard of comparison in most clinical trials.

On August 20, 1985, Imperial Chemical Industries, PLC ("ICI") obtained United States Patent 4,536,516 (the '516 Patent) for tamoxifen. In December 1985 Barr filed an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration ("FDA"), requesting approval to sell a generic bioequivalent version of the pioneer drug tamoxifen. An ANDA filing is governed by the Hatch-

1. Unless otherwise noted, the facts in this background are drawn from the Corrected Consolidated Class Action Complaint (the "Complaint") filed by Plaintiffs.

Appendix B

Waxman Act, 21 U.S.C. § 355, which provides an expedient method of obtaining FDA approval to bring generic bioequivalent drugs to the market. In addition to affirming that the generic drug contains the same active ingredient(s) as the patented drug already approved and listed by the FDA, an ANDA filer must certify why the patent would not be infringed pursuant to one of four reason:

I. No patent was in fact filed for the pioneer drug;

II. The patent for the pioneer drug has expired;

III. The patent for the pioneer drug will expire on a particular date *and* the ANDA filer will not market its generic product before that date; or

IV. The patent for the pioneer drug is invalid or will not be infringed upon the proposed generic product.

See 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV).

Upon the filing of an ANDA with a paragraph IV certification, the holder of the patent whose validity is being questioned may bring an action for declaratory judgment against the ANDA filer. Such a lawsuit has the effect of staying FDA consideration and approval of the ANDA for thirty months or until the date of a court decision as to the validity of the patent, whichever comes first. *See* 21 U.S.C. § 355(j)(5)(B)(iii). A court, in its discretion, however, may

extend the stay if the litigation is not resolved within the thirty month period. *See id.* One of the benefits of being the first ANDA filer to obtain FDA approval is an exclusive 180-day period in which to sell the generic drug free from other generic drug competition. *See* 21 U.S.C. § 355(j)(5)(B)(iv). The 180-day period of market exclusivity is triggered either by the first sale of the applicant's product or when a court determines either that the patent is invalid or will not be infringed, whichever is earlier.[2] *Id.*

Barr's ANDA application, as amended in September 1987, certified that the '516 Patent was invalid and unenforceable. Within forty-five days of receiving notice of Barr's ANDA application, ICI sued Barr for patent infringement in the Southern District of New York.[3] ICI's patent infringement suit against Barr was tried before the late Honorable Vincent L. Broderick. On April 20, 1992, Judge Broderick held that the '516 Patent was invalid and unenforceable because ICI wrongfully withheld relevant

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2. At the time of Barr's ANDA, the court determination trigger was interpreted to be a final, non-appealable decision by a court. In light of two subsequent district court decisions, the FDA amended its regulation defining "court action" so that a district court determination of patent invalidity is now considered to be a final decision triggering the 180-day exclusivity period. *See* 21 C.F.R. § 314.107(c) (interim rule).

3. ICI's lawsuit also named as a defendant Heumann Pharma GmbH & Company ("Heumann"), Barr's supplier of tamoxifen. Heumann was subsequently dismissed from the suit in accordance with the terms of a stipulation of settlement. According to the Complaint, Heumann agreed to be bound by any determination of the validity of the '516 Patent.

material from the United States Patent and Trademark Office. *Imperial Chem. Industries, PLC v. Barr Labs., Inc.*, 795 F.Supp. 619 (S.D.N.Y.1992) (" *ICI v. Barr* "). ICI appealed that determination to the Federal Circuit.

Zeneca and Barr Settle the Patent Infringement Dispute

In 1993, while the appeal was pending, Zeneca (which had recently succeeded to ICI's rights in the '516 Patent) and Barr entered into a settlement agreement (the "Settlement Agreement"). Pursuant to the Settlement Agreement, Barr withdrew its challenge to the validity of the '516 Patent and amended its ANDA application to certify that it would not seek to market its generic version of tamoxifen until the patent expired. In return, Zeneca paid Barr $21 million and licensed Barr to sell tamoxifen manufactured by Zeneca in the United States, including Puerto Rico and the District of Columbia. The Settlement Agreement was conditioned upon the Federal Circuit vacating Judge Broderick's judgement declaring the '516 Patent invalid.[4]

Plaintiffs allege that, as part of the Settlement Agreement, Barr and Zeneca also agreed that Barr would not commercially market its generic product to avoid triggering the 180-day exclusivity period. Zeneca and Barr's understanding allegedly was that, although Barr's ANDA application would be amended to paragraph III, if a subsequent ANDA filer successfully invalidated the '516

4. Zeneca also promised to pay Heumann a sum of cash equal to $9.5 million at the time of settlement and $35.9 million over a ten year period in exchange for Heumann's promise to discharge all claims related to the '516 Patent.

Patent then Barr would insist upon its exclusivity rights (as the first paragraph IV filer) and not commercially market the generic until 2002, thereby delaying the triggering of the 180-day exclusivity period.

Barr and Zeneca filed a Joint Motion to Dismiss the Appeal as Moot and to Vacate the Judgment Below. No copy of the Settlement Agreement was presented to the Court of Appeals. Sidmak Laboratories, Inc. ("Sidmak"), a generic drug manufacturer, sought leave to file, untimely, a brief as amicus curiae objecting to dismissal of the appeal. On March 19, 1993, the Federal Circuit granted the joint motion pursuant to its practice at the time to honor settlement agreements and denied Sidmak's motion. *See Imperial Chem. Indus., PLC v. Heumann Pharma GmbH & Co.*, 991 F.2d 811 (table) (Fed.Cir.1993).[5] On March 23, 1993 Judge Broderick vacated the judgement and dismissed the case. Consequently, the '516 Patent remained valid, and Zeneca's Nolvadex® brand and Barr's licensed version of tamoxifen were the only products on the market. Although Barr could produce tamoxifen at a lower cost than the price at which it obtains tamoxifen from Zeneca under license, Barr's ability

5. Since that time, the Supreme Court has ruled that federal appellate courts may not direct the *vacatur* of a district court order based solely on a settlement agreement between the parties. *See United States Bancorp Mortgage Co. v. Bonner Mall Partnership*, 513 U.S. 18, 27, 115 S.Ct. 386, 130 L.Ed.2d 233 (1994). However, the Federal Circuit subsequently held that *United States Bancorp* applied only to cases still pending when *United States Bancorp* was decided, and thus the *vacatur* (issued prior to *United States Bancorp*) was proper. *See Zeneca Ltd. v. Novopharm Ltd.*, 111 F.3d 144 (Table), 1997 WL 168318, at *2 (Fed.Cir.1997).

to price the licensed version is restrained by that higher cost.

Subsequent ANDAs for Tamoxifen

In June 1994, Novopharm Ltd. ("Novopharm") filed an ANDA for tamoxifen that claimed the '516 Patent was invalid.[6] Subsequently, on January 18, 1995 Zeneca sued Novopharm for patent infringement. Before discovery began, Novopharm moved for summary judgment on the basis that the *ICI v. Barr* Judgment should be given preclusive effect and that the *vacatur* should be ignored. (Change Dec., Ex. 8.) The district court disagreed. *Zeneca Ltd. v. Novopharm Ltd.*, 923 F.Supp. 74 (D.Md.1995). After discovery was completed, Novopharm again moved for summary judgment, this time arguing that the court should adopt two factual findings made in the vacated judgment in *ICI v. Barr* under the doctrine of issue preclusion. *Zeneca Ltd. v. Novopharm Ltd.*, 919 F.Supp. 193, 196 (D.Md.1996). Again the district court denied the motion, *id.* at 196-98, and subsequently found that Zeneca did not engage in inequitable conduct before the PTO, and therefore granted judgment to Zeneca upholding the validity of the '516 Patent. (Chang Dec., Exs. 9 and 10.) On appeal, the Federal Circuit affirmed the validity of the '516 Patent in an unpublished decision. *Zeneca Ltd. v. Novopharm Ltd.*, 111 F.3d 144, 1997 WL 168318 (Fed.Cir.1997) (Table).

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6. The facts about the Novopharm ANDA and subsequent litigation are not in the Complaint, but are based on court decisions publicly available on Westlaw and papers submitted to those courts. (*See* Chang Dec., Exs. 8-11).

Appendix B

In August 1994, Pharmachemie, B.V. ("Pharmachemie") submitted an ANDA with a paragraph III certification for its version of tamoxifen. In February 1996, Pharmachemie amended its ANDA to include a paragraph IV certification. Zeneca then sued Pharmachemie for patent infringement within 45 days of the amendment, *see Zeneca Ltd. v. Pharmachemie, B.V.*, Civ. 37 F.Supp.2d 85 (D.Mass.1999), triggering the statutory 30-month stay. The FDA gave tentative approval to Pharmachemie's ANDA on April 3, 1997. Before the 30-month stay expired, Zeneca moved the court to extend the stay. The motion was denied in a published decision. *Zeneca Ltd. v. Pharmachemie, B.V.*, 16 F.Supp.2d 112 (D.Mass.1998). Although not mentioned in the Complaint, prior to trial the district court granted Zeneca's motion for partial summary judgment on the issues of collateral estoppel, patent misuse, and unclean hands. *Zeneca Ltd. v. Pharmachemie, B.V.*, 37 F.Supp.2d 85 (D.Mass.1999). At trial, Pharmachemie argued that the '516 Patent was unenforceable because Zeneca had engaged in inequitable conduct before the PTO and that the patent was invalid because it did not set forth the "best mode" for carrying out the invention, as required by 35 U.S.C. § 112. *Zeneca Ltd. v. Pharmachemie, B.V.*, Civ. No. 96-21413(RCL), slip op. at 3 (D.Mass. Sept. 14, 2000). The court granted judgment as a matter of law to Zeneca on the inequitable conduct claim, and a jury returned a verdict in Zeneca's favor on the best mode claim. *Id.* at 4-5. No appeal was taken.

In January 1996, Mylan Pharmaceuticals, Inc. ("Mylan") submitted an ANDA with a paragraph IV certification for its version of tamoxifen. Zeneca sued Mylan in the Western District of Pennsylvania for patent infringement within

45 days of that certification, also thus triggering the 30-month statutory stay of FDA approval for Mylan's ANDA. Mylan then agreed to follow the *Pharmachemie* court's decision, and the case was dismissed after that court ruled in favor of Zeneca. *Zeneca Ltd. v. Mylan Labs.*, No. 96-333 (W.D.Pa. Nov. 30, 2000).

Barr's Petition to the FDA

While Mylan and Pharmachemie's actions were pending before the district courts, on June 26, 1998, Barr filed a Petition for Stay of Action with the FDA to block final marketing approval for Mylan's ANDA (the "FDA Petition"). Although Barr had amended its ANDA from a paragraph IV certification to a paragraph III certification after the *ICI v. Barr* settlement, Barr contended in its FDA Petition that it was entitled nonetheless to the 180-day exclusivity period as the first paragraph IV filer. The FDA acceded to Barr's petition and announced in a letter to Barr, dated March 2, 1999, that it would stay any approval of tamoxifen ANDAs until 180 days after the date of the first commercial marketing of the drug under Barr's ANDA or the date of a final court decision holding the tamoxifen patent to be invalid or not infringed.

Pharmachemie and Mylan later successfully challenged this decision in court. *Mylan Pharmaceuticals, Inc. v. Henney*, 94 F.Supp.2d 36, 54 (D.D.C.2000), *vacated as moot sub nom. Pharmachemie, B.V. v. Barr Labs., Inc.*, 276 F.3d 627 (D.C.Cir.2002). In response to the district court's order, on June 26, 2000 the FDA revoked Barr's eligibility for the 180-day exclusivity period.

Appendix B

Allegations Regarding Injury

Plaintiffs essentially allege that but for the Settlement Agreement, the judgment declaring the '516 Patent invalid would have been affirmed, Barr's 180-day exclusivity period would have been triggered, and a competitive market for tamoxifen would have resulted. Plaintiffs further allege that Zeneca and Barr maintain a duopoly in which Zeneca illegally shares its monopolistic profits with Barr through the licensing agreement. The discount for purchasing tamoxifen distributed by Barr is only about 5% compared to the price for Zeneca's brand name version, Nolvadex®. Plaintiffs allege that because the Settlement Agreement permits Zeneca and Barr to charge artificially inflated prices, Plaintiffs were overcharged for tamoxifen.

Procedural History

The Settlement Agreement has spawned thirty lawsuits around the country, all of which have been transferred to this Court, pursuant to 28 U.S.C. § 1407, by the Judicial Panel on Multi-District Litigation for coordination of pre-trial matters. A coordinated class action complaint was subsequently filed. The complaint alleges that the Settlement Agreement enabled Zeneca and Barr to (I) resuscitate a patent that Barr had established by clear and convincing evidence was invalid and unenforceable; (ii) confine the entire United States market for tamoxifen to one manufacturer, Zeneca; (iii) share the monopoly profits of Zeneca's tamoxifen; (iv) avoid price competition and maintain artificially inflated market prices for Nolvadex® and its Zeneca-manufactured generic licensed to Barr; and (v) exclude competition from

other generic manufacturers. (*See* Compl. ¶ 53.) The Complaint further alleges that but for the Settlement Agreement, Judge Broderick's judgment would have been affirmed, the FDA would have granted final approval to Barr's generic version of tamoxifen, Barr would have marketed a generic version of tamoxifen, a highly competitive market for tamoxifen would have developed after Barr's 180-day exclusivity period had run, and Zeneca would have been collaterally estopped from enforcing the '516 Patent against other ANDA filers. (*See id.* ¶ 54.) Plaintiffs also allege that by refusing to market a generic version of tamoxifen, Barr could prevent another challenger to the '516 Patent from being able to market the generic counterpart.

STANDARD FOR MOTION TO DISMISS

When deciding a motion to dismiss pursuant to Fed.R.Civ.P. 12(b)(6), the court must take all allegations in the complaint as true and draw all reasonable inferences in favor of the plaintiff. *Conley v. Gibson*, 355 U.S. 41, 45-46, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957); *Niagara Mohawk Power Corp. v. Federal Energy Reg. Comm'n*, 306 F.3d 1264, 1267 (2d Cir.2002). A complaint should not be dismissed "unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." *FD Property Holding, Inc. v. U.S. Traffic Corp.*, 206 F.Supp.2d 362, 369 (E.D.N.Y.2002) (internal quotation marks omitted). However, the Court may consider matters of public record, such as court decisions, statutes, and documents such as briefs filed with courts and other public bodies. *See, e.g., Papasan v. Allain*, 478 U.S. 265, 268, 106 S.Ct. 2932, 92 L.Ed.2d 209 n. 1 (1986) ("Although this case comes to us on

a motion to dismiss under Federal Rule of Civil Procedure 12(b), we are not precluded in our review of the complaint from taking notice of items in the public record . . . ."); *Rothman v. Gregor,* 220 F.3d 81, 92 (2d Cir.2000).

DISCUSSION

I. Whether the Settlement Agreement Violated the Sherman Act

A. General Principles

Section 1 of the Sherman Act provides: "Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal . . . ." 15 U.S.C. § 1.

As a general rule, an agreement between a monopolist and a potential competitor to divide the market between them and exclude other competition is per se illegal under Section 1. *See United States v. Topco Assoc., Inc.,* 405 U.S. 596, 608, 92 S.Ct. 1126, 31 L.Ed.2d 515 (1972) ("One of the classic examples of a per se violation of § 1 is an agreement between competitors at the same level of the market structure to allocate territories in order to minimize competition.").

However, the holder of a patent legally maintains a monopoly over his or her product and may "prevent other[s] from utilizing his discovery without his consent." *Zenith Radio Corp. v. Hazeltine Research, Inc.,* 395 U.S. 100, 135, 89 S.Ct. 1562, 23 L.Ed.2d 129 (1969). A patent holder also

"may assign to another his patent, in whole or in part, and may license others to practice his invention." *Id.* "Simply stated, a patent holder is permitted to maintain his patent monopoly through conduct permissible under the patent laws." *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1204 (2d Cir.1981).

This permissible conduct includes the settlement of patent litigation by a licensing agreement. *See Standard Oil Co. v. United States,* 283 U.S. 163, 170, 51 S.Ct. 421, 75 L.Ed. 926 (1931) ("Where there are legitimately competing claims or threatened interferences, a settlement by agreement, rather than litigation, is not precluded by the [Sherman] Act."); *Duplan Corp. v. Deering Milliken, Inc.*, 540 F.2d 1215, 1220 (4th Cir.1976) ("the settlement of patent litigation, in and of itself, does not violate the antitrust laws"); *Scientific Corp. v. Schneider (Europe) AG,* 983 F.Supp. 245, 269 (D.Mass.1997) ("It is well established that settlement of patent litigation through a cross-licensing agreement does not in and of itself violate the antitrust laws."), *appeal dism'd,* 152 F.3d 947 (Fed.Cir.1998) (Table).

B. Bad Faith Patent Settlements Can Violate the Antitrust Laws

A patentee, however, cannot go "beyond the limits of the patent monopoly." *United States v. Line Material Co.*, 333 U.S. 287, 308, 68 S.Ct. 550, 92 L.Ed. 701 (1948). As the Supreme Court held in *Standard Oil,* the very case that established that patent settlements do not alone violate the antitrust laws: " *Any* agreement between competitors may

be illegal if part of a large plan to control interstate markets." 283 U.S. at 169, 51 S.Ct. 421 (emphasis added).

For example, in *United States v. Singer Co.*, 374 U.S. 174, 83 S.Ct. 1773, 10 L.Ed.2d 823 (1963), Singer and a Swiss company Gegauf (along with a third Italian company) settled threatened and actual interference proceedings before the United States Patent Office (the precursor to the modern PTO) by, *inter alia*, cross-licensing patents regarding sewing machines to one another. Thereafter, Gegauf assigned its patent application to Singer which then received the patent. Evidence showed that Singer and Gegauf also sought the power to better enforce these patents against Japanese competitors who might seek to import sewing machines into the United States that infringed upon Gegauf's patents. *Id.* at 191, 195 n. 9, 83 S.Ct. 1773. Singer undertook steps to exclude the Japanese competition by bringing a proceeding before the United States Tariff Commission (which only an American company like Singer could do) to exclude all foreign machines that fell within *Gegauf's* patent from entering the United States. *Id.* at 194, 195-96. Although the District Court found that no illegal conspiracy existed because the primary purpose of the agreements was to settle the patent disputes, the Supreme Court reversed and found that Singer had gone beyond protecting its own patents and instead had combined with Gegauf against other competitors. *Id.* at 194, 83 S.Ct. 1773. In his concurring opinion, Justice White was most troubled by the possibility that by not pursuing the interference claims, Singer and Gegauf collusively deprived the Patent Office of notice of prior art that would sap the proposed patent of the novelty that justifies

a patent monopoly in the first place. *Id.* at 199-200, 83 S.Ct. 1773 (White, J., concurring).

As explained by the Fourth Circuit,

> It is only when settlement agreements are entered into in bad faith and are utilized as part of a scheme to restrain or monopolize trade that antitrust violations occur . . . . *Singer* makes clear that it is not the mere act of settlement but the intent of the parties in entering into that settlement and their actions pursuant thereto that, in law constitute such a violation [of the Sherman Act].

Duplan Corp., 540 F.2d at 1221-22.[7] In other words, Plaintiffs can establish a Sherman Act violation by alleging facts from which it can be inferred that Zeneca and Barr entered into the Settlement Agreement in bad faith and used the agreement to restrain or monopolize trade.

C. Application of Antitrust Laws to Patentee-ANDA Applicant Settlements

In opposition to the motion to dismiss, Plaintiffs point out that at least three courts have reviewed allegedly bad faith settlements between patentees and ANDA filers and found that Sherman Act claims can be stated for reasons similar to those set forth in *Singer*. Plaintiffs argue that this

7. In *Duplan Corp.*, the court held that the illegality of such an agreement could not be presumed solely by the existence of a letter from a settling party's attorney opining that the party would prevail if it pursued the patent infringement case. 540 F.2d at 1221.

case is comparable to these other cases, and that their allegations accordingly state a claim under the Sherman Act. Because each case arises under its own complex set of facts, those facts are set forth here in some detail.

1. Terazosin Hydrochloride

Abbott Laboratories registered patents regarding the drug terazosin hydrochloride ("terazosin") and received approval to market it for the treatment of hypertension and enlarged prostate. *See In re Terazosin Hydrochloride Antitrust Litig.*, 164 F.Supp.2d 1340, 1343 (S.D.Fla.2000), *pet. appeal granted*, No. 02-101-71-J (11th Cir. Apr. 19, 2002). Subsequently two generic manufacturers, Zenith Goldline Pharmaceuticals, Inc. and Geneva Laboratories, filed ANDAs with paragraph IV certifications challenging the validity of Abbott's patents and began racing toward first approval from the FDA. *Id.* at 1343-44. By late March 1998, although Abbott was engaged in infringement litigation with both challengers, the 30-months stays were expiring and both Zenith and Geneva were posed to being marketing generic versions of terazosin. *Id.* at 1345-46.[8]

However, Abbott settled its litigation with Zenith by paying $3 million up front, and $6 million per quarter on condition that Zenith did "not sell, offer for sale, donate or

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8. With regard to Zenith, on October 1, 1997, Zenith's motion for preliminary injunctive relief was denied. *Terazosin*, 164 F.Supp.2d at 1345. Zenith's appeal of that order was pending before the Federal Circuit when the parties settled. *Id.* at 1346. With regard to Geneva, patent infringement litigation was proceeding apace in the Northern District of Illinois.

otherwise commercially distribute in the United States" terazosin, and upon Zenith's promise not to assist any other company to gain FDA approval to market terazosin. *Id.* at 1346. With regard to Geneva, Abbott agreed to pay $4.5 million per month to Geneva to refrain from marketing any generic terazosin until any other generic began selling or until Geneva received a final, unappealable judgment that its generic terazosin did no infringe Abbott's patents. *Id.* However, Geneva and Abbott would continue to litigate the issue, but Geneva would support Abbott in extending the 30-month stay and promised "to use its best efforts to oppose any attempt by any ANDA applicant" to market generic terazosin prior to the date provided for in then-existing FDA regulations. *Id.* at 1347 n. 7. In other words, *Terazosin* involved two simultaneous horizontal agreements-one permanently ending possible competition from Zenith, and another buying time and cooperation from Geneva.

In an antitrust action, the district court found that by these agreements "Geneva and Zenith foreswore competing with Abbott in the United States market for terazosin hydrochloride drugs and promised to take steps to forestall others from entering the markets in exchange for millions of dollars . . . ." *Id.* at 1348-49. The court held that such agreements were blatantly anti-competitive by dividing the market among competitors (a horizontal restraint) and that such agreements were illegal *per se. Id.*

2. Cardizem CD

Marion Merrell Dow ("Dow") introduced in 1982 a new pioneer drug (diltiazem hydrochloride) for treating

hypertension and angina that was patented and marketed in a once-daily, immediate-release delivery method under the name Cardizem. *In re Cardizem CD Antitrust Litig.*, 105 F.Supp.2d 618, 629 (E.D.Mich.2000) ("*Caridzem I*"). Eventually, the product was improved by releasing it in a once-daily "sustained release" delivery method produced under license from a separate patent holder ("Elan"), and rebranded as Cardizem CD. *Id.* In 1992, Biovail International Corporation began developing its own once-daily generic of Cardizem, and began working with Hoechst-Roussel Pharmaceuticals ("HRP") to develop a sustained release delivery method of its own to be called Tiazac. *Id.* Upon HRP's filing an ANDA stating that Tiazac did not infringe on Cardizem's patents, Dow sued for patent infringement on November 11, 1993.

In late 1994, HRP's parent Hoechst AG agreed to acquire Dow, and HRP ended its partnership with Biovail. *Id.* at 630. Biovail in turn sued Hoechst for breach of contract and antitrust violations, and the parties reached a master settlement of both litigations in 1995 in which they agreed not to challenge each others' respective products. *Id.* After an FTC investigation into the Hoechst-Dow merger, Hoechst agreed to support Biovail's applications to the FDA for approval of Tiazac by directing the FDA to reference Biovail's applications with its own studies used for Cardizem. *Id.* The only remaining barrier to Tiazac's entry to the market was an outstanding patent dispute between Biovail and Elan over the delivery method. *Id.* When Hoechst discovered that the Biovail-Elan litigation would be settled, however, and that Biovail intended to file a New Drug Application (rather than an ANDA) to avoid the 180-day exclusivity period to

which another generic manufacturer (Andrx) already had claim, Hoechst refused to permit Biovail to reference the studies. *Id.* Accordingly, without clinical studies that Biovail could reference, the FDA refused to license Tiazac. *Id.* at 631.

Meanwhile, in September 1995 Andrx had filed its ANDA certifying that Cardizem would not be infringed, and Hoechst sued for patent infringement in January 1996 thereby triggering the 30-month stay. *Id.* On September 17, 1997, the FDA preliminarily approved Andrx's generic version of Cardizem CD, which meant that Andrx could have begun marketing the product as early as July 4, 1998. *Id.* at 632. Shortly thereafter, Hoechst and Andrx entered into an agreement, by the terms of which Andrx would refrain from marketing its generic version of Cardizem CD until all appeals in the litigation were concluded and would receive quarterly payments of $10 million from Hoechst beginning on July 9, 1998. *Id.*

By August 20, 1998, consumer plaintiffs began filing lawsuits alleging violations of indirect purchaser state laws. *Id.* On June 9, 1999, Hoechst settled its patent litigation with Andrx by paying Andrx an additional $50 million. *Id.* The district court held that the agreement was a naked restraint on trade subject to *per se* analysis, and granted plaintiffs partial summary judgment. *See In re Cardizem Antitrust Litig.*, 105 F.Supp.2d 682, 699-705 (E.D.Mich.2000) ("*Cardizem II* "), *appeal filed,* No. 00-2483 (6th Cir. Dec. 19, 2000).

3. Procardia XL

Pfizer, Inc. ("Pfizer") filed a New Drug Application for extended release nifedipine, a hypertension treatment, which Pfizer markets in three strengths (30, 60 and 90 mg) under the brand name Procardia XL. *See Biovail, Inc. v. Mylan Labs, Inc., et al.*, Civ. No. 1:01CV66, slip op. at 5 (N.D.W.Va. Mar. 22, 2002). In April 1997, Mylan filed an ANDA for 30 mg nifedipine with the FDA. *Id.* Pfizer sued Mylan for patent infringement, and the case settled in March 2000, under terms by which Mylan received a license for a "private label" version of Procardia, and Mylan would not market its generic version covered by its ANDA. *Id.*, slip op. at 5-6.

Biovail filed its ANDA for 30 mg and 60 mg nifedipine after Mylan's filing, but was unable to market either version until one of its licensees forced the FDA's hand by petitioning for final approval, which the FDA granted on February 6, 2001. *Id.*, slip op. at 6. The FDA ruled that Mylan had effectively converted its paragraph IV certification to a paragraph III certification upon settling with Pfizer, and that marketing the "private label" version triggered the 180-day exclusivity period. *Id.*, slip op. at 6-7.

Biovail then sued Mylan and Pfizer for unreasonably restraining trade by agreeing to reduce competition and hindering Biovail's entry into the market for four months. Biovail claimed that because buyers in the market for Procardia XL prefer to obtain different dosage strengths from the same supplier, the restrictions on 30 mg Procardia XL prevented Biovail from marketing effectively its 60mg version. *Id.* The district court found that these allegations

were sufficient to state a claim that Mylan and Pfizer conspired to produce anti-competitive effects. *Id.*, slip op. at 11.

D. Analysis

Defendants claim that the Settlement Agreement at issue here is unlike the agreements found suspect in other cases, and that it is a defensible resolution of patent litigation and not a restraint of trade. Further, Defendants argue that further inquiry into the vacated decision "would effectively strip settlements of value and finality by permitting collateral suits by third parties who were allegedly deprived of a 'favorable' decision." (Def. Consolidated Reply Mem. at 7.)

1. Plaintiff's Claims Are Not an Impermissible Collateral Attack on the *Vacatur* Order

Defendants argue that *vacatur* was an appropriate course for the Federal Circuit to take given precedent current at the time. (Def. Consolidated Mem. at 27-30), a point which Plaintiffs do not contest. (Pl. Opp. Mem. at 45.) Defendants further argue that Plaintiffs' claims are fundamentally inconsistent with the *vacatur*; comparing this to a collateral attack on a judgment. However, there is a difference. As noted by Defendants, with *vacatur* potential future litigants (such as Plaintiffs) are no worse off because "the only damage to the public interest is that the validity of [the intellectual property rights] *would be left to future litigation.*" *Major League Baseball Properties, Inc. v. Pacific Trading Cards, Inc.*, 150 F.3d 149, 152 (2d Cir.1998) (settlement of trademark dispute) (emphasis added).

Plaintiffs are not trying to deprive the settlement of its value to either party, since both parties have apparently received the benefit of the bargain-Zeneca was able to eliminate a significant challenge to the validity of its '516 Patent, and Barr was well compensated. If Plaintiffs can allege facts that the Settlement Agreement was executed in bad faith, they will have stated a claim that the Settlement Agreement was an illegal restraint of trade. Accordingly, this Court will examine whether the allegations in the Complaint state claims as a matter of law.

2. The Zeneca-Barr Settlement Agreement is Different from Other Patentee-ANDA Agreements

Defendants claim that even if settlements between patentees and ANDA filers are not immunized from antitrust scrutiny, the Settlement Agreement between Zeneca and Barr is significantly different from those found in other cases to violate the Sherman Act. Defendants are correct.

a. The Settlement Agreement Terminated the Entire Litigation

One crucial difference is that the Settlement Agreement in fact ended the litigation outright. Barr and Zeneca actually resolved their complex litigation, and in so doing they cleared the field for other generic manufacturers to challenge the patent. Indeed, at least three other generic manufacturers accepted the challenge, filed ANDAs with paragraph IV certifications, and in each case, Zeneca successfully litigated the validity of the '516 patent.

In comparison, in *Cardizem,* Hoechst paid Andrx to refrain from marketing its generic after the 30 months stay expired, but did not otherwise end the litigation. 105 F.Supp.2d at 632. Similarly, in *Terazosin,* the patentee settled outright one case (the Zenith Agreement), but took advantage of the existence of a second case to prolong the 30 month stay. 164 F.Supp.2d at 1346-47. Of course, these sorts of agreements sap a generic filer's motivation to finish the litigation, and therefore produce a perverse result under the Hatch-Waxman Act by providing an incentive to delay the patent litigation without "clearing the way" for other ANDA filers. In the end, these agreements meant that the litigation could drag on without providing other generic manufacturers (even those who were not sued for patent infringement like Biovail) a means by which to enter the market.

The same cannot be said about the present agreement. The conclusion of the litigation meant that other ANDA filers were free to litigate the validity of the '516 patent. Instead of leaving in place an additional barrier to subsequent ANDA filers, the Settlement Agreement in fact removed one possible barrier to final FDA approval-namely, the existence of ongoing litigation between an existing ANDA filer and a subsequent filer.

b. Barr's FDA Petition Five Years After the Settlement Agreement Cannot Serve as a Basis for Liability

Plaintiffs contend that Defendants' argument regarding "clearing the field" for other ANDA filers is belied by Barr's FDA Petition (allegedly pursuant to the Settlement

Agreement) that sought to preserve Barr's 180-day exclusivity period. Barr's FDA Petition was premised on an interpretation of FDA regulations that only Barr's own marketing of a generic version of tamoxifen or a final court decision could trigger the 180-day period. Given the existence of two pending infringement suits, Barr's FDA Petition sought to assert that its previous ANDA was superior in determining who might receive the 180-day exclusivity period.[9]

Two of the bases for the FDA Petition came only years after the Settlement Agreement. First, until 1997, FDA regulations interpreting the 180-day exclusivity period made it clear that the ANDA filer which first successfully defended against the patent infringement suit would receive the 180-day exclusivity period. The relevant language of the Hatch-Waxman Act provides, however, that a subsequent ANDA paragraph IV application "shall be made effective not earlier than one hundred and eighty days after-(I) the date [the] Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or (II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to

9. It must be noted that Barr did *not* seek similar relief when Novopharm filed its ANDA and challenged the '516 patent between 1994 and 1997. Only after the events in 1997 and 1998 described above in the text did Barr attempt to assert its rights. If Barr intended to protect its exclusivity period on behalf of itself and Zeneca *pursuant to the Settlement Agreement,* Barr's inactivity during the pendency of the Novopharm litigation is inexplicable.

be invalid or not infringed, whichever is earlier." 21 U.S.C. 355(j)(5)(B)(iv).

In light of the actual language of the Hatch-Waxman Act, in 1997 a district court invalidated the FDA's "successful defense" regulation on the grounds that it contradicted the unambiguous language of the Hatch-Waxman Act. *See Mova Pharmaceutical Corp. v. Shalala,* 955 F.Supp. 128 (D.D.C.1997) (enjoining FDA from giving final approval to second ANDA filer who successfully defended against patent infringement suit). The Court of Appeals for the District of Columbia Circuit upheld this decision on the grounds that the successful defense regulation was inconsistent with the statutory language and that the plain meaning of the statutory language would not produce an absurd result. *See Mova Pharmaceutical Corp. v. Shalala,* 140 F.3d 1060, 1070-73 (D.C.Cir.1998).

In other words, until 1997, if Novopharm, Pharmachemie or Mylan had successfully defended against Zeneca's patent infringement suit, the first one to do so would receive the 180-day exclusivity period pursuant to then-existing FDA regulations. After the *Mova Pharmaceutical* decisions in 1997 and 1998, Barr's claim to the 180-day exclusivity period was strengthened significantly (if not wholly created) since the FDA could not permit the applications of the other generic manufacturers to take effect until 180 days elapsed after such a court decision.

Second, the FDA specifically argued in the *Mova Pharmaceutical* appeal that its regulations requiring that an ANDA filer who loses the patent infringement suit be treated

as a paragraph III filer was "housekeeping" and not intended to affect the application of the 180-day exclusivity period. *Id.*, 140 F.3d at 1070. Although the D.C. Circuit confessed some disbelief at this interpretation, it was willing to defer to the FDA's interpretation regarding an issue not directly before the court. *Id.* at 1070 n. 13 ("We confess to not understanding how the FDA can reconcile its reading with the language of its own regulation, but stress that this issue has not been briefed and is not necessary to the decision in this case.")[10]

Two months after the D.C. Circuit's decision in *Mova Pharmaceutical,* Barr filed its FDA Petition. Barr argued that the Hatch-Waxman Act, as interpreted by the D.C. Circuit, required that the FDA stay approval of Mylan's ANDA application since the FDA regulation requiring a "successful defense" were no longer valid. Barr also used the FDA's own arguments before the D.C. Circuit to support its position that, notwithstanding the paragraph III amendment Barr filed after the Settlement Agreement, it should be entitled to the 180-day exclusivity period whenever and by whomever the period was triggered.

Barr's FDA Petition was thus an attempt to petition a governmental body in order to protect an arguable interest in a statutory right based on recent developments in the court

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10. The district court that reviewed the FDA's decision to grant Barr's FDA Petition criticized and rejected this confusing interpretation of the interplay between paragraph III and paragraph IV certification. *See Mylan Pharm. v. Henney,* 94 F.Supp.2d 36, 57 (D.D.C.2000), *vacated as moot sub nom., Pharmachemie B.V. v. Barr Labs., Inc.,* 276 F.3d 627 (D.C.Cir.2002).

and at the FDA. As such, the FDA Petition was protected activity under the First Amendment, and long-settled law established that the Sherman Act, with limited exceptions, does not apply to petitioning administrative agencies.[11] *See Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 81 S.Ct. 523, 5 L.Ed.2d 464 (1961) (Sherman Act does not apply to joint lobbying of state legislature); *United Mine Workers of America v. Pennington*, 381 U.S. 657, 85 S.Ct. 1585, 14 L.Ed.2d 626 (1965) (extending *Noerr* to joint activity to persuade administrative agency). Of course, as described below, plaintiffs are also unable to allege any anti-competitive impact from Barr's FDA Petition, both because the FDA's decision in Barr's favor

11. Plaintiffs admit they cannot and do not seek to argue that Barr's FDA Petition falls within the sham exception to the *Noerr-Pennington* doctrine. (Pl. Opp. Mem. at 52-53.)

Given the disposition of these motions, this Court need not address the more difficult question of whether the Settlement Agreement itself is protected by the *Noerr-Pennington* doctrine. *Compare Hise v. Philip Morris, Inc.*, 46 F.Supp.2d 1201, 1206 (N.D.Okla.1999), *aff'd*, 208 F.3d 226, 2000 WL 192892 (10th Cir.2000) (holding that concerted activities *among co-defendants* in jointly negotiating Master Settlement Agreement with 46 states and 6 other jurisdictions was protected activity) *with Cardizem*, 105 F.Supp.2d at 641 (collecting and agreeing with cases that hold settlements *between adverse parties* are not protected); *see* Raymond Ku, *Antitrust Immunity, the First Amendment, and Settlements: Defining the Boundaries of the Right to Petition*, 33 Ind. L.Rev. 385, 429 (2000) (arguing that *Noerr-Pennington* would not apply because "when asked to approve a settlement agreement, a court is not being asked to determine liability or approve the substance of the agreement.").

was overturned, *see Mylan Pharm. v. Henney,* 94 F.Supp.2d 36, 57 (D.D.C.2000), *vacated as moot sub nom., Pharmachemie B.V. v. Barr Labs., Inc.,* 276 F.3d 627 (D.C.Cir.2002), and because no generic manufacturer in fact ever received approval to enter the market.

c. The Allegations Lack the Continuing Behavior Found in Other Cases

The present case is also different in that no pattern of settlements or continuing behavior is involved. For example, in *Singer,* doubts arose over Singer's petition to the Tariff Commission because of references to another company (Pfaff) in Gegauf's assignment of rights. Singer and Gegauf returned to the negotiating table to delete those references, a "maneuver . . . for the purpose, as the trial court found, of giving Singer a better chance of prevailing before the Tariff Commission in its efforts to exclude infringing machines." *Singer,* 374 U.S. at 196, 83 S.Ct. 1773. The Court found that the conspiracy was "clearly illustrated" by this type of continuing behavior of Singer and Gegauf. *Id.* at 195, 83 S.Ct. 1773.

No similar maneuvering or continued behavior is alleged here. Certainly, there are no allegations that Zeneca and Barr ever acted in concert after the 1993 Settlement Agreement, and only one allegation (the Barr FDA Petition) of any allegedly anti-competitive activity after the Settlement Agreement was executed. Indeed, the only pattern of behavior discerned from the Complaint appears to be a vigorous defense of the '516 patent. Zeneca challenged every ANDA filer, and defeated the claims of patent invalidity on the merits

on two occasions (not including Mylan's decision to tie its fate to Pharmachemie's). While there may conceptually be a case where bad faith can be alleged based on a single event, the allegations here do not state a claim for bad faith settlement.

II. Plaintiffs Have Not Suffered Antitrust Injury

Plaintiffs' Sherman Act claims also fail to adequately plead antitrust injury. In order to state a claim under the Sherman Act, a plaintiff must allege facts that in addition to causation show "antitrust injury, which is to say [1] injury of the type the antitrust laws were intended to prevent and [2] that flows from that which makes defendants' acts unlawful. The injury should reflect the anticompetitive effect either of the violation or of anticompetitive acts made possible by the violation." *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489, 97 S.Ct. 690, 50 L.Ed.2d 701 (1977).

A. Plaintiffs Suffered No Injury From the Settlement Agreement Because No Manufacturer Ever Received Approval to Market Generic Tamoxifen

The injury here (higher prices for tamoxifen) resulted from the existence of the '516 patent and not the Settlement Agreement, and because the purported injury flowed from the result of a lawful patent monopoly, no antitrust injury can exist. For example, in *NYNEX v. Discon, Inc.*, 525 U.S. 128, 119 S.Ct. 493, 142 L.Ed.2d 510 (1998), the Supreme Court held that no injury flowed from a regional Bell

operating company's unilateral decision to refuse to deal with one company. *Id.* at 136-37, 119 S.Ct. 493. Similarly, no antitrust injury occurs when a patent holder sues for infringement unless the patent was fraudulently procured or the infringement action was a sham. *In re Independent Service Orgs. Antitrust Litig.*, 203 F.3d 1322, 1326 (Fed.Cir.2000). Nor can a defendant in a patent infringement suit claim antitrust injury based on the costs of defending against the infringement or related costs caused by losing the infringement suit. *Eastman Kodak Co. v. Goodyear Tire & Rubber Co.*, 114 F.3d 1547, 1558 (Fed.Cir.1997), *partially overruled on other grounds by, Cybor Corp. v. FAS Tech, Inc.*, 138 F.3d 1448 (Fed.Cir.1998) (en banc).

Plaintiffs contend that Defendants caused injury because the Settlement Agreement was structured to license tamoxifen to Barr only at supra-competitive prices. (Pl. Opp. Mem. at 35.) Plaintiffs thus argue that this case is similar to *Ciprofloxacin,* where the court found that the allegation that the patentee would have negotiated licenses with generic manufacturers at *competitive* prices sufficed to allege antitrust injury. 166 F.Supp.2d 740, 749 (E.D.N.Y.2001). Even liberally interpreting the Complaint to encompass such allegations (which it does not) and despite the language in *Ciprofloxacin,* Defendants are correct to the extent that Plaintiffs are alleging injury based on the possibility that Zeneca would license its patent at competitive prices. As the Federal Circuit has noted, "[t]here is no reported case in which a court ha[s] imposed antitrust liability for a unilateral refusal to sell or license a patent." *Independent Service Orgs.*, 203 F.3d at 1326 (internal quotations omitted). No antitrust

injury can flow from the prices at which Zeneca licensed tamoxifen to Barr.

Plaintiffs' injuries thus must flow from the anti-competitive nature of the Settlement Agreement. As described above, this would entail proof of injury not from the decision by Zeneca to settle the patent litigation, but from the exclusion of other competitors in the market. However, as Defendants note, no generic manufacturer ever obtained FDA approval to bring the drug to market since all three manufacturers who filed with paragraph IV certifications failed to prove in court that the patents were invalid.

Antitrust injury, however, must be caused by something other than the regulatory action limiting entry to the market. For example, no antitrust injury was found where a potential competitor to a local electrical utility in Pittsburgh merged with the existing utility before receiving permission to compete from the state regulatory agency. *City of Pittsburgh v. West Penn Power Co.*, 147 F.3d 256, 267-68 (3d Cir.1998). Similarly, another court has found that no antitrust injury existed to support an antitrust counterclaim brought by a second ANDA filer since it would not be able to compete in the market until (1) the patent was declared invalid and (2) the 180-day exclusivity period expired for the first filer. *See Bristol-Myers Squibb v. Copley Pharm., Inc.*, 144 F.Supp.2d 21, 23 (D.Mass.2000).

In the present case, the lack of competition in the market was not caused by the deployment of Barr's exclusivity period, but rather by the inability of the generic companies to invalidate or design around the '516 Patent. Indeed, in

Bristol-Myers, supra, the possibility of antitrust injury was more proximate since the second ANDA filer would have been able to enter the market relatively soon after the first ANDA filer. Here, absent any allegations that Barr conspired with Zeneca somehow to hinder either Novopharm, Pharmachemie or Mylan from establishing the invalidity of the '516 patent, there is no basis for the claim that competition could have existed. In this respect, the present case is quite different from *Terazosin,* where Geneva had received approval to begin marketing a generic capsule of terazosin, or from Procardia XL case, where Biovail in fact received approval to market its generic version despite the allegedly anti-competitive efforts to delay its entry.

Plaintiffs do argue that Barr's FDA Petition delayed approval of Mylan's ANDA, and that therefore this action prevented Mylan from marketing its generic version of tamoxifen. (Pl. Opp. Mem. at 37.) Even assuming that the Complaint alleges that Mylan would have marketed its generic tamoxifen before receiving a court order in its favor,[12] given the actual judgment against it in favor of Zeneca, Mylan never could have entered the market without infringing upon the '516 Patent. Plaintiffs, in other words, allege injury based on the lack of competition that could have only existed by illegally infringing on the '516 Patent. The lack of

12. The Complaint merely alleges that *Barr* (in its FDA Petition) claimed that Mylan "likely will begin marketing a generic version upon receiving FDA approval." (Compl.¶ 66.) This is somewhat different from *Plaintiffs* claiming that Mylan would enter the market before actually obtaining a declaration that the '516 Patent was invalid (and thus risking monetary liability for infringing on the patent).

competition was not the result of any anti-competitive conduct by Zeneca or Barr, but rather the result of the existence of the '516 patent and the decision by the patent holder to enforce it. It is thus not antitrust injury, but rather the result of the legal monopoly that a patent holder possesses. *Cf. Eastman Kodak,* 114 F.3d at 1558 ("The cause of [claimant's] injuries was not that Eastman enforced the [acquired] patent, but that the patent was enforced at all. These injuries, therefore, did not occur 'by reason' of that which made the acquisition allegedly anticompetitive.").

B. Plaintiffs Cannot Allege Antitrust Injury Based on the Settlement Agreement Resuscitating the '516 Patent

Plaintiffs' other claim of injury is essentially that the settlement and *vacatur* deprived other generic manufacturers of the ability to make the legal argument that the *ICI v. Barr* judgment (if affirmed) would collaterally estop Zeneca from claiming the '516 patent was valid in future patent litigation with other ANDA filers. At the time of settlement, however, Barr had no vested right in the judgment still on appeal. *See Asselta v. 149 Madison Ave. Corp.,* 79 F.Supp. 413, 415 (S.D.N.Y.1948) ("A complainant has not any vested right in the decree of the district court while it is subject to review."). If Barr had no such right, it is hard to imagine how other generic manufacturers had legitimate expectations that they could rely upon the judgment on appeal as well. Yet Plaintiffs now seek to base an injury upon the elimination of a judgment on which not even Barr could rely. Plaintiffs point to no case that establishes this result, namely, that forcing other generic

manufacturers to litigate the validity of the '516 patent, is an injury to competition.

It must be noted that in light of the Federal Circuit's later decision in *Novopharm* affirming a district court's decision *upholding* the validity of the '516 patent, plaintiffs' supposition that the Federal Circuit would have affirmed Judge Broderick's decision declaring the '516 patent invalid is also unwarranted. Of course, the *Novopharm* decision could not prevent other generic manufacturers from challenging the patent. *See Ethicon, Inc. v. Quigg,* 849 F.2d 1422, 1429 (Fed.Cir.1988) (Federal Circuit's prior decision upholding patent's validity not binding on another challenge in the courts or the Patent and Trademark Office); *Allen Archery, Inc. v. Browning Mfg. Co.,* 819 F.2d 1087, 1091 (Fed.Cir.1987) (a manufacturer charged with patent infringement will not be collaterally estopped from challenging the validity of the patent as part of its defense to the infringement claim even if the patent's validity was upheld in a prior infringement suit involving a different manufacturer). And when Pharmachemie and Mylan continued their challenges to the validity of the '516 patent even after the *Novopharm* decision, that decision had no impact on the merits of their claims. As noted previously, those challenges failed as well.

Absent any cognizable injury, the Sherman Act claim is dismissed.

III. The Claims for Restitution

Count II alleges that under state common law (*see* Pl. Opp. Mem. at 61) Zeneca has benefitted from unlawfully charging supra-competitive prices, that Barr has benefitted from unlawfully receiving payments from Zeneca and receiving funds from the sales of the licensed tamoxifen to the Plaintiffs, and that therefore equity demands that Defendants disgorge these benefits. (Com pl. ¶¶ 108-115.)

Under the current Draft Restatement, "[a] person who is unjustly enriched at the expense of another is liable in restitution to the other." Restatement (Third) of Restitution & Unjust Enrichment § 1 (Discussion Draft Mar. 31, 2000). Plaintiffs are correct that the state of the common law most likely recognizes unjust enrichment as a source of obligation with its own remedial structure. However, a restitution claim requires that Defendants have "unjustly," *id.*, or "wrongfully" received a benefit. *Geller v. County Line Auto Sales, Inc.*, 86 F.3d 18, 22 (2d Cir.1996).

Plaintiffs' allegations of enrichment focus entirely upon the ability of Zeneca and Barr to charge monopolistic prices for tamoxifen after the Settlement Agreement. As held above, based on plaintiffs' allegations there was nothing impermissible about Zeneca charging monopolistic prices or licensing tamoxifen to Barr. Since whatever benefit received by Zeneca or Barr was not wrongfully secured, no restitution is available. *Id.* ("Because the defendants were not unjustly enriched, a restitution award is not available.") Count II of the Complaint thus is also dismissed.

Appendix B

IV. Plaintiffs' Other State Law Claims

A. Antitrust Claims

Plaintiffs bring state law claims under the antitrust laws of 17 states: Arizona, California, the District of Columbia, Florida, Kansas, Louisiana, Maine, Massachusetts, Michigan, Minnesota, New Jersey, New York, North Carolina, North Dakota, South Dakota, West Virginia, and Wisconsin. Plaintiffs and Defendants agree that state antitrust law should be construed similarly to federal antitrust law where possible.[13] (*See* Def. Consolidated Mem. at 36 and n. 15 (collecting cases and official opinions); Pl. Opp. Mem. at 69 n. 39 (collecting more cases and noting statutory directives).) Accordingly, since Plaintiffs fail to state a claim under the Sherman Act, and since the state antitrust law claims are based on the same allegations, those claims are also dismissed.

B. Unfair Competition and Consumer Protection Laws

Plaintiffs also assert that the Defendants' actions violated consumer protection and unfair competition laws in 21 states: Arizona, California, Florida, Kansas, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Minnesota, Nevada, New

13. The parties disagree on one point not relevant to the present discussion-whether the *Illinois Brick* rule (prohibiting indirect purchasers from asserting federal antitrust claims) also governs state antitrust law claims where the states in question have not definitively ruled on the issue. Since the allegations otherwise fail to state a claim, this disagreement is immaterial.

Jersey, New Mexico, New York, North Carolina, North Dakota, South Dakota, Tennessee, Vermont, West Virginia, and Wisconsin.

These state unfair competition laws generally prohibit sellers from engaging in unfairly competitive practices (such as agreements to divide the market) or otherwise making false promises or misrepresentations to the consumer public. Plaintiffs' claims sound wholly in allegations of unfair competition based on the Settlement Agreement that track entirely the allegations underlying the antitrust claims.

However, in order to state a claim under state unfair competition laws related to the enforcement of a patent, "bad faith must be alleged and ultimately proven." *Zenith Electronics Corp. v. Exzec, Inc.*, 182 F.3d 1340, 1355 (Fed.Cir.1999). Otherwise, the claims are preempted by patent law. *Id.* For the reasons already noted, the Complaint fails to allege facts that indicate that Zeneca and Barr acted in bad faith in settling their patent litigation for purposes of federal law. The same result governs the state law claims.

Accordingly, the state unfair competition law claims are also dismissed.

Appendix B

CONCLUSION

For the foregoing reasons, the motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) is granted.

SO ORDERED.

Dated: May 13th, 2003
Brooklyn, New York

s/ I. Leo Glasser
I. Leo Glasser
United States District Judge

APPENDIX C — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT DENYING PETITION FOR REHEARING FILED SEPTEMBER 14, 2006

UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

Roseann B. MacKechnie
CLERK

Date:	
Docket Number:	03-7641-cv
Short Title:	In Re: Tamoxifen Citrate Antitrust Litigation v.
DC Docket Number:	01-md-1408
DC:	EDNY (BROOKLYN)
DC Judge:	Honorable I. Glasser

At a stated term of the United States Court of Appeals for the Second Circuit, held at the Danie Patrick Moynihan United States Courthouse, 500 Pearl Street, in the City of New York, on the 14 day of September two thousand six.

In Re: Tamoxifen Citrate Antitrust Litigation

JOBLOVE, ALLIED SERVS., DIV WELFARE FUND, BENNISH, KOONAN, GREAT LAKES HEALTH PLAN INC , LACAVA, DONEGA, SMITH, LOVINGER, WOOLLACOTT, WHITESIDE, PLATT, UNDERWOOD, TEAMSTERS LOCAL 237, LYNCH, CALLAWAY, MALONEY, MECHANICAL CONTRACT, IBEW-NECA LOCAL 505 HEALTH & WELFARE PLAN, A.F. OF L.-A.G.C. BUILDING TRADES WELFARE FUND, SHEET

Appendix C

METAL WORKERS LOCAL 441 HEALTH & WELFARE PLAN, LOCAL 1199 NAT'L BENEFIT FUND FOR HEALTH & HUMAN SERVICES, NEW YORK STATEWIDE SENIOR ACTION COUNCIL, MARKS, BLONSTEIN,

Plaintiffs - Appellants

v.

BARR LABS, INC., ASTRAZENECA PHARMACEUTICALS LP, ZENECA INC., ASTRAZENECA PLC,

Defendants - Appellees.

A petition for panel rehearing and a petition for rehearing en banc having been filed herein by the Plaintiffs-Appellants. Upon consideration by the panel that decided the appeal, it is Ordered that said petition for rehearing is **DENIED**.

It is further noted that the petition for rehearing en banc has been transmitted to the judges for the court in regular active service and to any other judge that heard the appeal and that no such judge has requested that a vote be taken thereon.

For the Court,
Roseann B. MacKechnie, Clerk

By: s/ [illegible]
Motion Staff Attorney

APPENDIX D — DISSENT FROM ORIGINAL OPINION DATED NOVEMBER 2, 2005

UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

August Term, 2003

(Argued: July 12, 2004 Decided: November 2, 2005

Docket No. 03-7641

In Re: Tamoxifen Citrate Antitrust Litigation

JOBLOVE, ALLIED SERVS., DIV WELFARE FUND, BENNISH, KOONAN, GREAT LAKES HEALTH PLAN INC., LACAVA, DONEGA, SMITH, LOVINGER, WOOLLACOTT, WHITESIDE, PLATT, UNDERWOOD, TEAMSTERS LOCAL 237, LYNCH, CALLAWAY, MALONEY, MECHANICAL CONTRACT, IBEW-NECA LOCAL 505 HEALTH & WELFARE PLAN, A.F. OF L.-A.G.C. BUILDING TRADES WELFARE FUND, SHEET METAL WORKERS LOCAL 441 HEALTH & WELFARE PLAN, LOCAL 1199 NAT'L BENEFIT FUND FOR HEALTH & HUMAN SERVICES, NEW YORK STATEWIDE SENIOR ACTION COUNCIL, MARKS, BLONSTEIN,

Plaintiffs-Appellants,

- v -

BARR LABS. INC., ASTRAZENECA PHARMACEUTICALS LP, ZENECA INC., ASTRAZENECA PLC,

Defendants-Appellees.

Appendix D

POOLER, *Circuit Judge*:

I respectfully dissent. I believe that the opinion of the court, which dismisses plaintiffs' complaint at the Rule 12(b)(6) stage, shortcuts a process necessary to balance the interests at stake in this litigation. These interests include, on one side, the encouragement of innovation fostered by the patent laws, the public and private interest in amicable settlements, and judicial economy; and, on the other side, an interest in vigorous competition protected by the Sherman Act as well as the interest of consumers in having the validity of a patent litigated. I agree with the majority that balancing is required but differ from them as to (1) the proper balancing analysis, and (2) the ability to perform this analysis without further development of the factual record. In my view, plaintiffs' allegations were sufficient to allow discovery and, thereafter, a more fully informed balancing analysis.

BACKGROUND

I. Plaintiffs' relevant allegations.

Plaintiffs allege that the various agreements described in the majority opinion are a cover for an agreement to allow Zeneca[33] and Barr to monopolize and allocate the tamoxifen market. In support of this proposition, plaintiffs further allege that (1) at the time the two drug manufacturers entered into their agreements, Zeneca's patent had been declared invalid by a district court and Zeneca's appeal was fully briefed

33. Like the majority, I use "Zeneca" to refer collectively to defendants Zeneca, Inc., Astrazeneca Pharmaceuticals LP, and AstraZeneca, Inc. "Barr" refers to defendant Barr Labs, Inc.

before the Federal Circuit; (2) Zeneca agreed to pay Barr $21 million and Barr's supplier $45.4 million in return for Barr's agreement to withdraw its challenge to Zeneca's patent and refrain from entering the generic market until Zeneca's patent expired in 2002; (3) the amount paid to Barr exceeded the amount that Barr could have earned by successfully defending its judgment because the 180-day period during which Barr would have been the only generic manufacturer would have been followed immediately by a highly competitive generic market; (4) although the agreement required Barr to convert its paragraph IV certification to a paragraph III certification, it also provided that Barr could revert to a paragraph IV certification if Zeneca's patent was later declared invalid, which would allow Barr and Zeneca to delay the entry of any subsequent generic challenger into the market; (5) in order to render the agreement effective, Barr was required to join Zeneca in moving for vacatur of the judgment, which motion resulted in the vacatur of the district court's determination that the patent was not valid; (6) subsequent generic challengers faced a thirty-month stay before they could enter the market; (7) Barr did indeed employ its exclusivity period against another generic manufacturer, Mylan Pharmaceuticals, when the latter was poised to enter the market; and (8) the savings to end purchasers who bought the tamoxifen that Barr obtained from Zeneca was only about 5% as compared to the 30% to 80% discount typically available where there is true generic competition.

Appendix D

II. The majority's analysis.

The majority's resolution of this appeal rests on a series of premises. First, the majority states that the Sherman Act aims to encourage competition by prohibiting agreements that unreasonably restrain trade. The majority next states that the patent laws also ultimately aim to stimulate competition and innovation, but that they do so through a system that grants an inventor a time-limited exclusive right in her invention or formulation. These contrasting goals, the majority posits, create a tension in cases where patent and antitrust overlap and require "a delicate balance." *Id.* (quoting *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1067 (11th Cir.2005)).

After thus recognizing the inherent tension between antitrust and patent law, the majority goes on to articulate principles that it believes should be used to resolve this tension in the context of an antitrust challenge to a Hatch-Waxman settlement agreement. First, it notes the general principle that settlements, including patent settlements in the pharmaceutical area, are to be encouraged because they promote the public interest and the interests of the parties. In addition, the majority relies on the Supreme Court's recognition that " 'where there are legitimately conflicting [patent] claims . . . a settlement by agreement rather than litigation, is not precluded by the Sherman Act.' " *Id.* (quoting *Standard Oil Co. v. United States*, 283 U.S. 163, 171, 51 S.Ct. 421, 75 L.Ed. 926 (1931)).

The majority then suggests that rules that severely restrict patent settlements create undue uncertainty concerning

patents and thus might delay the entry of innovative products into the market. It also reasons that, although forcing patent litigation to continue might be pro-competitive in some cases, resolving disputes may also allow the entry into the market of valuable inventions.

Turning to the agreements at issue in this case, the majority states that it cannot find them unreasonable based on the likelihood that Barr would maintain its victory on appeal because courts are ill positioned to predict the outcome of litigation. Puzzlingly, after noting that the validity of a settlement agreement must be judged from the viewpoint of the time in which it was made, the majority relies on the fact that other district courts reached a different conclusion from that of the Southern District of New York to show that it is difficult to assess Barr's likelihood of success on appeal. It finds "of little moment" the fact that the parties reached settlement "after the district court ruled against Zeneca" because all parties have a motivation to eliminate risk on appeal, but finds it significant "[t]hat Zeneca had sufficient confidence in its patent to proceed to trial rather than find some means to settle the case first."

The court concludes "that without alleging something more than the fact that Zeneca settled after it lost to Barr in the district court," plaintiffs have not alleged an antitrust violation. The first "something more" that the majority considers is the $21-million reverse payment Zeneca made to Barr in return for the latter's agreement to stay out of the generic market for tamoxifen and to cooperate in vacating its favorable judgment. It finds no per se bar to reverse payments, indicating that "the fact that the patent holder is

paying to protect its patent monopoly [does not], without more, establish[ ] a Sherman Act violation." The majority also posits that reverse payments are to be expected in the drug patent context because Hatch-Waxman shifted the risk of a lawsuit from an infringer to a patent holder.

Next, after conceding that reverse payments that, like the one alleged here, exceed the profits the generic might expect to make if it prevailed in the underlying litigation look suspicious, the majority holds that such excessive reverse payments are not unlawful, explaining that "so long as the patent litigation is neither a sham nor otherwise baseless, the patent holder is seeking to arrive at a settlement in order to protect that to which it is presumably entitled: a lawful monopoly over the manufacture and distribution of the patented product."

The court then articulates its standard for judging whether a Hatch-Waxman settlement agreement violates the antitrust laws: "[A]bsent an extension of the monopoly beyond the patent's scope . . . and absent fraud . . . the question is whether the underlying infringement lawsuit was 'objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits.' " *Id.* (quoting *Prof'l Real Estate Investors, Inc. v. Columbia Pictures, Inc.*, 508 U.S. 49, 60, 113 S.Ct. 1920, 123 L.Ed.2d 611 (1993)). The majority then holds that plaintiffs did not and cannot-in light of Zeneca's subsequent litigation victories-establish that Zeneca's infringement suit against Barr was objectively baseless.

Appendix D

The majority next considers whether the exclusionary effects of the agreements exceed the patent's scope and concludes that they do not because (1) the agreements did not bar the introduction of any non-infringing products; (2) they ended all litigation between Zeneca and Barr, thus opening the field to other generic challengers; and (3) they did not entirely foreclose competition because they allowed Barr to market Zeneca's version of Tamoxifen. Finally, the majority considers plaintiffs' allegations concerning Barr's manipulation of the exclusivity period. It concludes that although "an agreement to time the deployment of the exclusivity period to extend a patent's monopoly power might well constitute anticompetitive action outside the scope of a valid patent," because the agreements themselves did not exceed the scope of Zeneca's lawful patent, Barr's actions could not be unlawful as in furtherance of an original conspiracy.

The court dismisses as speculative any claim by plaintiffs that Barr and Zeneca entered into a side agreement that Barr would use its exclusivity period in the way it did, claiming that "[a]lthough the Agreement in this case did include a provision allowing Barr to revert its paragraph III certification back to a paragraph IV certification in the event another generic manufacturer successfully invalidated the patent, it seems farfetched, in light of the law at the time, to construe the provision as a conscious and unlawful attempt to manipulate the exclusivity period." The law to which the majority refers is a former federal regulation requiring that in order to obtain an exclusivity period, the generic manufacturer must successfully defend a patent infringement suit. *See Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1065

(D.C.Cir.1998) (citing former 21 C.F.R. 314.107(c)(1)). The majority also argues that Barr's deployment of the exclusionary period is adequately explained "by [its] own interest in protecting itself from competition through a petition to the FDA for a statutorily described benefit" and that nothing in the complaint suggests a conspiracy. Alternatively, the majority suggests that it has grave doubts that the injury plaintiffs allege is antitrust injury because the injury stemmed from the scope of Zeneca's patent and from the inability of other generics to defeat Zeneca's patent.

DISCUSSION

I differ with both the majority's standard for pleading a Hatch-Waxman-settlement antitrust violation and with several subsidiary holdings, conclusions, or assumptions. The requirement that-unless an antitrust plaintiff demonstrates that a settlement agreement exceeds the scope of the patent-it must show that the settled litigation was a sham, i.e., objectively baseless, before the settlement can be considered an antitrust violation is not soundly grounded in Supreme Court precedent and is insufficiently protective of the consumer interests safeguarded by the Hatch-Waxman Act and the antitrust laws. Beyond that overarching difference, the majority has, in my view, wrongly (1) accorded dispositive deference to Zeneca's patent rights when its patent had been declared invalid at the time of the settlement; (2) focused on subsequent litigation concerning patent validity rather than the litigation posture at the time of settlement; (3) held that the district court could not assess the likelihood that Zeneca would succeed on appeal; (4) held that plaintiffs insufficiently alleged a conspiracy between

Barr and Zeneca to deploy Barr's paragraph IV certification when it would delay the market entry of another generic manufacturer; and (5) failed to recognize that whether plaintiffs' injuries stem from the alleged Barr/Zeneca conspiracy or from the failure of other generics to invalidate the patent cannot be resolved on the pleadings.

I. The pleading standard.

Relying principally on *Professional Real Estate Investors*, the majority concludes that, in order to attack a Hatch-Waxman settlement on antitrust grounds, plaintiffs must allege either that the agreement gave the patent holder benefits beyond the scope of the patent or that the agreement was a sham, that it was "objectively baseless in the sense that no reasonable litigant would realistically expect success on the merits." Majority op. (quoting 508 U.S. at 60, 113 S.Ct. 1920). I agree that a settlement agreement that confers on the patent holder a greater monopoly benefit than does the patent itself is illegal. However, I do not agree that, absent a showing of benefits exceeding the scope of the patent, the antitrust plaintiff must show that the settled litigation was objectively baseless.

Professional Real Estate Investors is not apposite because it did not involve the settlement of Hatch-Waxman patent litigation. Rather, plaintiffs brought a copyright infringement case, and defendants countersued, alleging that the suit was a sham and a violation of §§ 1 and 2 of the Sherman Act. 508 U.S. at 52, 113 S.Ct. 1920. The district court held that while no infringement occurred, no antitrust violation occurred either because the plaintiffs were entitled

to immunity under *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 81 S.Ct. 523, 5 L.Ed.2d 464 (1961), as their litigation "was clearly a legitimate effort and therefore not a sham." 508 U.S. at 53, 113 S.Ct. 1920 (quoting *Columbia Pictures Indus., Inc. v. Prof'l Real Estate Investors, Inc.*, 1990 WL 56166 at * 1 (C.D.Cal.1990)). Both the Court of Appeals and the Supreme Court agreed, and the Supreme Court defined "sham" for the purposes of defeating *Noerr-Pennington* immunity,[34] as the majority does here. *Id.* at 60, 113 S.Ct. 1920. The Court was not called upon to decide and did not decide the standard for pleading an antitrust violation; it simply defined "sham," in a context in which it was already clear that the required standard was sham litigation. It is ill-advised, I think, to import the definition of "sham" used where a party must concededly establish that litigation was "sham" to avoid a well-established immunity from antitrust liability to a context in which we are defining antitrust liability in the first instance. Although Zeneca's original suit was likely protected under the standard set out in *Professional Real Estate Investors*, it does not necessarily follow that the settlement of that suit should be judged on the same grounds.

In fact, other leading cases cited in the majority opinion suggest, although I concede they do not mandate, a contrary conclusion. *See Standard Oil*, 283 U.S. at 180, 51 S.Ct. 421 (noting in the context of upholding cross-licensing

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34. *Noerr-Pennington* immunity derives from both *Noerr* and *United Mine Workers of Am. v. Pennington*, 381 U.S. 657, 85 S.Ct. 1585, 14 L.Ed.2d 626 (1965).

agreements for patents against an antitrust challenge that a "master found, after an elaborate review of the entire art, that the presumption of validity attaching to the patents had not been negatived in any way; that they merited a broad interpretation; that they had been acquired in good faith; and that the scope of the several groups of patents overlapped sufficiently to justify the threats and fears of litigation."); *United States v. Singer Mf'g Co.*, 374 U.S. 174, 197, 83 S.Ct. 1773, 10 L.Ed.2d 823 (1963) (White, *Justice, concurring*) (noting that the majority had not reached issue of whether "collusive termination of a Patent Office interference proceeding pursuant to an agreement between [certain parties] to help one another to secure as broad a patent monopoly as possible, invalidity considerations, notwithstanding" was sufficient, standing alone, to state an antitrust claim and indicating that he believed it was). Both the majority opinion in *Standard Oil* and the concurrence in *Singer* suggest that an antitrust court must go beyond deciding that a lawsuit was not a sham, that is objectively baseless, before it can dismiss an antitrust challenge to the lawsuit's settlement-as opposed to the initiation of the lawsuit-and, in fact, must consider the strength of the patent.

Holding that a Hatch-Waxman settlement agreement cannot violate antitrust laws unless the underlying litigation was a sham also ill serves the public interest in having the validity of patents litigated. *See United States v. Glaxo Group Ltd.*, 410 U.S. 52, 57, 93 S.Ct. 861, 35 L.Ed.2d 104 (1973). This interest exists because "[i]t is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be

protected in his monopoly."[35] *Id.* at 58, 93 S.Ct. 861. Litigating the validity of drug company patents is critically important to the general well being in light of the recent trend toward capping the maximum amounts insurers and public benefit plans will spend on medications.

A Hatch-Waxman settlement, by definition, protects the parties' interests as they see them. Whether it also promotes the public's interest depends on the facts. If the validity of the patent is clear, and the generic company receives a license to market the patent holder's product, competition is increased. However, if, as in this case, the patent has already been shown to be vulnerable to attack and the generic manufacturer is paid to keep its generic product off the market, it is hard to see how the public benefits.

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35. The majority suggests, that this interest was adequately protected through the subsequent suits by other generics. I disagree. This position ignores the time gap between the Barr-Zeneca litigation and the subsequent litigation. During this period, had Barr maintained its victory on appeal, which, as I explain below, was quite likely, very ill consumers would have had access to low cost generic tamoxifen. In addition, once Zeneca's patent protection was gone with respect to Zeneca, it was gone with respect to all generic manufacturers, which would have produced a very competitive market at the close of the 180-day exclusivity period. Thus, it was very important to the public interest that Barr and Zeneca allow the appeal to proceed. This does not mean, as the majority suggests that any settlement of patent litigation after the challenger prevails at trial is an antitrust violation. As I discuss below, a Hatch-Waxman settlement agreement, even on appeal from a judgment declaring the patent invalid, is not a per se antitrust violation. Rather, a reviewing court must assess the reasonability of the settlement by weighing various factors including the strength of the patent as it appeared at the time of settlement.

Appendix D

The Hatch-Waxman Act provides an incentive for the second kind of agreement that other patent laws do not provide. Patent litigation other than Hatch-Waxman patent litigation generally proceeds along familiar lines. A patent holder sues an alleged infringer, and the infringer either chooses to go to trial to vindicate its view that the patent is invalid or pays the patent holder money as compensation for damages the patent holder has suffered or as the price of a license. In this context, one can perhaps assume that the parties' relative views on the strength of a patent will result in a pro-competitive or neutral result. If the patent holder believes its patent is strong, it will proceed to trial, knowing that it can collect damages at the end. The generic manufacturer, if it believes the patent holder's patent is weak, may be willing to risk damages and market its product during the litigation, thereby promoting competition. And if the claims are in relative equipoise, a licensing arrangement may well result.

In contrast, a generic competitor subject to Hatch-Waxman cannot enter the market for the first thirty months after litigation is commenced against it. *See* 21 U.S.C. § 355(j)(5)(B)(iii). In addition, whether its attack against the patent is strong or weak, the benefit it will obtain by successfully litigating to the finish is not great. At best, it will obtain 180 days in which it will be the exclusive generic on the market. *See* 21 U.S.C. § 355(j)(5)(B)(iv). On the other hand, the benefits to the public from the completion of litigation can be enormous if the generic challenger prevails as it did, at least initially, here. Once the 180-day exclusivity period is over, any generic that wishes to market a generic product and that can establish its product is bioequivalent to

the patented product can enter the market, thus providing increased competition.

Moreover, the thirty-month stay provides an incentive to the patent holder to pay its generic competitor more than the generic company could have realized from winning the lawsuit. This is so because once the settlement is reached and the litigation dismissed, another generic manufacturer will have to wait at least thirty months after litigation is commenced against it to begin production.[36] Thus, the patent holder will be protected against all generic competition for thirty months after the first lawsuit is terminated. This problem is aggravated when the agreement between the putative competitors provides that the generic company can deploy its exclusivity period after sitting on it until another ANDA applicant attempts to enter the market. These anti-competitive effects—and others not present in this case—have caused antitrust scholars to propose various analytical frameworks for determining whether an antitrust violation has occurred when a patent holder makes a reverse payment to settle patent litigation. The analytical frameworks proposed vary both as to burden of proof and as to the evidence necessary to find a reverse payment illegal.

For instance, Herbert Hovenkamp, Mark Janis, and Mark A. Lemly propose that a Hatch Waxman Act settlement that includes a reverse payment be presumed illegal with the

36. Of course, other generic challengers could file Paragraph IV certifications before the first litigation is resolved, but a second generic manufacturer has little incentive to incur the cost of litigation. Even if it wins, it will have to wait until after the first generic challenger's exclusivity period has expired to market its product.

patent holder being allowed to rebut this presumption "by showing both (1) that the ex ante likelihood of prevailing in its infringement lawsuit is significant, and (2) that the size of the payment is no more than the expected value of litigation and collateral costs attending the lawsuit." Herbert Hovenkamp et al, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L.Rev. 1719, 1759 (2004).

Daniel A. Crane urges a standard somewhat more favorable to the settling parties. *See* Daniel A. Crane, *Ease Over Acuracy in Assessing Patent Settlements*, 88 Minn. L.Rev. 698, 709 (2004) (urging that the dispositive factor should be "the ex ante likelihood that the defendant would be excluded from the market if the case was finally adjudicated"). *Id.* at 709. Because the settling parties will typically have the most documentation relevant to the issue, he contends that "there is relatively little social cost in requiring the settling parties to retain documents going to the core issues in the patent infringement lawsuit." *Id.* However, to avoid unduly chilling patent settlements, Crane, unlike Hovenkamp et al, would not shift the burden of proof to the settling parties. *Id.*

Thomas F. Cotter's approach occupies the middle ground. Cotter would leave on the antitrust defendants the burden of demonstrating the legality of a reverse-payment settlement, but he does not adopt Hovenkamp's position that the reverse payment must be limited to litigation costs. *See* Thomas F. Cotter, *Refining the "Presumptive Illegality" Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis and Lemley*, 87 Minn. L.Rev. 1789, 1795-97, 1802 (2003). Rather, he

argues that "when the antitrust defendants can show that the payment is below the expected amount of the patent defendant's loss if an injunction were to issue, the burden of proving validity and infringement should be somewhat easier to satisfy than at a full-blown infringement trial." *Id.* at 1814. Cotter rejects, and the other commentators implicitly reject, the approach adopted by the majority. *See id.* at 1811 (noting that requiring antitrust plaintiffs to show that patent litigation is a sham "would permit too many anticompetitive settlements to escape scrutiny. A suit with only a 25% chance of success may not be a sham, but a settlement based upon such a low probability estimate reduces consumer welfare for no apparent offsetting benefit.") (footnote omitted).

Thus, commentators, precedent, and policy suggest the majority's requirement that an antitrust plaintiff show that a Hatch-Waxman lawsuit settled by agreement was a sham-assuming that the agreement did not convey benefits beyond the scope of the patent-is unjustified. A more searching inquiry and a less stringent standard are required to properly protect all interests. I see no reason why the general standard for evaluating an anti-competitive agreement, i.e., its reasonableness, should not govern in this context.[37]

37. The majority argues that applying the general rule of reasonableness would "mak[e] every settlement of patent litigation, at least in the Hatch-Waxman Act context, subject to the inevitable, lengthy and expensive hindsight of a jury as to whether the settlement constituted a 'reasonable' restraint (and, in this case, whether the Federal Circuit would have affirmed or reversed in a patent appeal)" and thus "place a huge damper on such settlements." I doubt that this doomsday scenario would, in fact, take place. Courts would eventually develop rules for judging the reasonableness of a

(Cont'd)

See Clorox. Co. v. Winthrop, Inc., 117 F.3d 50, 56 (2d Cir.1997). In assessing reasonableness, the fact-finder must consider all the circumstances affecting a restrictive agreement. *Id.* Of course, the strength of the patent must be central to any antitrust analysis involving a patent. Thus, in assessing the reasonability of a Hatch-Waxman settlement, I would rely primarily on the strength of the patent as it appeared at the time at which the parties settled and secondarily on (a) the amount the patent holder paid to keep the generic manufacturer from marketing its product, (b) the amount the generic manufacturer stood to earn during its period of exclusivity, and (c) any ancillary anti-competitive effects of the agreement including the presence or absence of a provision allowing the parties to manipulate the generic's exclusivity period. Because plaintiffs allege that the district court's determination of patent invalidity would have been upheld on appeal; that Barr received more than it would have through a victory on appeal; and that Barr and Zeneca agreed that Barr would deploy its paragraph IV certification to defeat other potential generic entrants, I believe that their pleading is adequate.

(Cont'd)

settlement, and as with other litigation, the majority of cases would be resolved in motion practice. Moreover, the majority again emphasizes the acknowledged interest in settlements without acknowledging the absent party in Hatch Waxman litigation settlements, the consumer of medicines. Those consumers have no ability to affect the settlement, which, in some cases, may benefit both parties beyond any expectation they could have from the litigation itself while harming the consumer. There is a panglossian aspect to the majority's tacit assumption that the settling parties will not act to injure the consumer or competition.

Appendix D

II. Ancillary issues.

A. Capacity of the district court to evaluate Zeneca's likelihood of success on appeal.

It appears that the court may have been motivated to adopt the "sham" or objectively baseless standard because it overestimated the difficulty of estimating Zeneca's chance of prevailing on appeal. *See* Majority op. (citing principally *Whitmore v. Arkansas*, 495 U.S. 149, 159-60, 110 S.Ct. 1717, 109 L.Ed.2d 135 (1990), for the proposition that is impossible to predict the likelihood that Barr would have maintained its patent victory on appeal). *Whitmore*, is inapposite; there the Court considered a challenge to one inmate's death sentence from a different inmate, Whitmore, who also had been sentenced to death. 495 U.S. at 153, 110 S.Ct. 1717. Whitmore argued that he had standing because Arkansas's Supreme Court compared the circumstances of any capital case currently before it to prior capital cases to determine whether the death penalty had been arbitrarily applied. *Id.* at 156, 110 S.Ct. 1717. Whitmore claimed that if he obtained federal habeas relief in the future *and* if he were again convicted and sentenced to death *and* appealed to the Arkansas Supreme Court, the failure to include the first inmate's heinous crime in the data base the Arkansas Supreme Court considered would prejudice the review of his sentence. *Id.* at 156-57, 110 S.Ct. 1717. The Court dismissed as speculative the probability of Whitmore's obtaining federal habeas relief, the odds that he would be retried, convicted and sentenced to death once more, and the odds "that the addition of [the first inmate's] crimes to a comparative review 'data base' would lead the Supreme Court of Arkansas to set

aside a death sentence for Whitmore." *Id.* at 157, 110 S.Ct. 1717. To find that the sequence of events Whitmore alleged would actually occur indeed requires multiple layers of speculation. In contrast, by the time of the settlement, Barr had already prevailed at the district court level. The record in that case is presumably available, the standards of review the appellate court would have employed are well known, and it is not outside the bounds of the district court's competence to predict whether Barr would have prevailed on appeal.[38] Judges and juries routinely perform an analogous,

38. The majority also relies on *Boehm v. Comm'r*, 146 F.2d 553 (2d Cir.1945), *aff'd*, 326 U.S. 287, 66 S.Ct. 120, 90 L.Ed. 78 (1945). This case also is strikingly inapposite; the *Boehm* court held only that a taxpayer must claim a loss in the year it becomes obvious and cannot rely on the inherently speculative outcome of litigation seeking to recover some of that loss to justify claiming it in a later year. 146 F.2d at 555. The relevance of that principle to the case at hand is not immediately obvious to me. It is also interesting to note that the Supreme Court affirmed not on the impossibility of predicting litigation outcome but rather because the Tax Court had found that the suit had "no substantial value" and "[t]here was no evidence in the stipulation of the merits of the suit, the probability of recovery or any assurance of collection of an amount sufficient to pay the creditors' claim . . . and to provide a sufficient surplus for stockholders." 326 U.S. at 294, 66 S.Ct. 120. The majority's additional reliance on *Asahi Glass Co. v. Pentech Pharms*, 289 F.Supp.2d 986, 993 (N.D.Il.2003), and *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F.Supp.2d. 188, 200-01 (E.D.N.Y.2003), requires little discussion. The statement quoted from *Asahi Glass* that "[n]o one can be *certain* that he will prevail in a patent suit"-is irrelevant to the capacity of skilled corporate counsel and district court judges to evaluate the likelihood that a determination of patent invalidity will be upheld, and the discussion in *Ciprofloxacin* relies primarily on *Whitmore* and *Boehm*, which I have already discussed.

but more difficult, task in legal malpractice cases in which they must estimate whether, absent attorney error, a party would have prevailed at trial. Estimating the possibility of success on appeal with the assistance of the full record and the parties' briefs is much simpler. Certainly the review would not be so difficult as to justify a sham litigation test.

B. The strength of Zeneca's patent.

As the majority states, the reasonableness of agreements under antitrust law must be judged by the circumstances existing at the time when the agreements were made . *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1207 (2d Cir.1981) ("Because the essence of a patent is the monopoly or exclusionary power it confers upon the holder; analyzing the lawfulness of the acquisition of the patent [within an antitrust analysis] necessitates that we primarily focus upon the circumstances of the acquiring party and the status of the relevant product and geographic markets at the time of acquisition."). When the agreements here were reached, Judge Broderick had found by clear and convincing evidence that Zeneca's patent was invalid. Therefore, the patent could no longer be considered presumptively valid. *See Shelcore, Inc. v. Durham Indus., Inc.*, 745 F.2d 621, 624-25 (Fed.Cir.1984) ("The presumption of validity does not guide our analysis on appeal. Rather, we review the findings and conclusions of a district court under the appropriate standard of review.")

The majority, citing *Rosco, Inc. v. Mirror Lite Co.*, 304 F.3d 1373, 1377-78 (Fed.Cir.2002), appears to suggest that *Shelcore* is no longer good law and that patents are presumed

valid on appeal even if they have been declared invalid by the district court. I respectfully suggest that the majority places too much weight on *Rosco*. The *Rosco* court simply reiterated the statutory language indicating that patents are presumed valid. 304 F.3d at 1377. It then held that the district court had improperly found that plaintiffs produced clear and convincing evidence to overcome this presumption and thus reversed its finding of validity as to one patent. *Id.* at 1378-79. This analysis is a far cry from a statement that a patent must be presumed valid on appeal because the latter holding would imply-contrary to *Shelcore* and Federal Rule of Civil Procedure 52(a)-that the district court's factual findings in support of its ultimate conclusion of invalidity are entitled to no deference.

Alternatively the majority suggests that it is not important where the presumption of validity lay at the moment of appeal because the patent holder was still entitled to protect its monopoly. However, even assuming, contrary to my view, that most patent settlements should be subject to the "sham litigation" standard, surely there are strong policy reasons for applying more searching scrutiny where a court of competent jurisdiction has found the patent to be invalid.

C. The majority's reliance on Zeneca's subsequent litigation victories.

The majority also focuses on the subsequent litigation between other generics and Zeneca to demonstrate that plaintiffs cannot support a claim that Zeneca's litigation against Barr was sham litigation. Of course, in my view, plaintiffs need not plead or prove sham or objectively baseless

litigation. But, in addition, the majority's discussion of the later litigation appears to violate its own acknowledgment of the basic principle that "the reasonableness of agreements under the antitrust laws are to be judged at the time they are entered into." Majority op. (quoting *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1306 (11th Cir.2003) (citing, *inter alia*, *SCM Corp.*, 645 F.2d at 1207)). At the time Zeneca and Barr settled the appeal, the existing facts made it fairly likely, if not certain, that Barr would prevail. Judge Broderick had judged the credibility of the witnesses and found that Zeneca willfully withheld information from the FDA. That finding is quintessentially factual. Thus, the Federal Circuit could have set it aside only for clear error. Fed.R.Civ.P. 52(a). Without the record, I cannot say that the Federal Circuit would have been required to affirm, but, as I am sure the majority will concede, it is the rare case in which an appellate court sets aside a trial court's credibility findings.[39] Had Barr prevailed, on appeal, as I expect it would have, Zeneca would have been estopped from asserting the validity of its patent in any subsequent litigation. Therefore, there is a certain unfairness in using the subsequent litigation, which would not have existed had Barr prevailed on appeal, to demonstrate that plaintiffs cannot establish that Barr would have prevailed on appeal.[40]

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39. I do not find persuasive the statistics the majority cites on the frequency of reversal in the Federal Circuit. These statistics would include decisions construing the patent and making other legal determinations. Therefore, they do nothing to show how frequently the Federal Circuit reverses credibility determinations on appeal.

40. I recognize that it makes more sense to use the subsequent litigation to argue that plaintiffs could not prove the Zeneca lawsuit was not a sham. However, as noted, I do not believe this is an appropriate test.

Appendix D

D. Conspiracy to use Barr's paragraph IV certification in an anticompetitive manner.

I turn now to the majority's expressed belief that the complaint cannot be read to plausibly allege a conspiracy between Barr and Zeneca to deploy Barr's putative exclusivity period to their joint benefit and to the detriment of other potential competitors and consumers. A complaint need "include only 'a short and plain statement of the claim showing the pleader is entitled to relief.' " *Swierkiewicz v. Sorema*, 534 U.S. 506, 512, 122 S.Ct. 992, 152 L.Ed.2d 1 (2002) (quoting Fed.R.Civ.P. 8(a)(2)). A simplified notice pleading standard is acceptable because "liberal discovery rules and summary judgment motions" allow the parties "to define disputed facts and issues and to dispose of unmeritorious claims." *Id.* The majority requires more than *Swierkiewicz* mandates when it complains of plaintiffs' failure to plead evidentiary facts that create an inference of conspiracy.

The court additionally attacks the plausibility of plaintiffs' allegations because, at the time Barr and Zeneca entered into their agreements, a generic enjoyed the benefit of the exclusivity period only if it had successfully defended an infringement lawsuit. *See Mova Pharm.*, 140 F.3d at 1065 (citing former 21 C.F.R. § 314.107(c)(1)). This regulation was struck down after the agreements at issue. *See id.* at 1076. Because the regulation was in effect when Barr and Zeneca finalized their agreement, the majority finds it implausible that they could have envisioned any anti-competitive effect from the portion of the agreement allowing Barr to deploy its exclusivity period if another generic manufacturer

succeeded in invalidated Zeneca's patent. That inference is certainly one that a reasonable fact finder could draw from the facts alleged to date. However, a reasonable fact-finder could also conclude that it is quite unlikely that sophisticated parties would include in their agreement a provision that had no potential benefit to either of them. Is it not at least as likely that the parties were conscious that the regulation was vulnerable to attack and that they wished to add another layer of protection against potential competitors in the event the regulation was invalidated? Discovery would presumably produce materials relevant to determining whether this provision was part of an antitrust conspiracy between Barr and Zeneca. Among other things, the parties may have had written communications concerning the purpose of the exclusionary-period clause. If not, the corporate employees who negotiated the agreement could be deposed. And, the parties could explore the state of legal discussion concerning the successful-defense requirement at the time of the agreement. Thus, it is premature to reject out of hand plaintiffs' claim that Barr and Zeneca agreed to the exclusivity-period provision because they wanted to further restrict other generic manufacturers' ability to market Tamoxifen.

E. Antitrust injury.

In addition to affirming dismissal of the paragraph IV certification claim because plaintiffs did not adequately describe an antitrust violation, the majority states that it has "grave doubt as to whether, even if the defendants agreed to deploy the exclusionary period to protect their shared monopoly power, the injury that the defendants allege they

suffered in this regard constitutes 'antitrust injury.' " The majority's doubt stems, in part, from Zeneca's victories in subsequent patent litigation. Because these victories could not have existed if (1) the settlement agreement had not been signed and (2) Barr had prevailed on appeal, they are not finally determinative of causation. Therefore, it is necessary to assess the strength of Zeneca's patent in order to decide whether the injuries were really caused by the patent itself or by the agreements.

III. The inappropriateness of dismissal at the Rule 12(b)(6) stage.

Applying the reasonableness inquiry that I suggest requires a factual record not yet in existence. We have no sense of the value to Barr of the exclusivity period it gave up or the relationship of the value of this period to the reverse payment Zeneca made. Nor do we have any sense of the negotiations between the parties concerning the provision that allowed Barr to revivify its Paragraph IV certification. Finally no judge or appellate panel has attempted to discern whether Judge Broderick's findings of facts were clearly erroneous. Allowing the parties to develop a record and make summary judgment motions would give the district court information it needs to assess the reasonableness of the agreements.

However, even under the majority's newly articulated standard, I believe that it was wrong to affirm the dismissal. At a minimum, the plaintiffs should be allowed to develop a factual record to demonstrate that Zeneca's litigation was sham because they had no reason to anticipate the standard

articulated here. I note that the courts that have finally rejected antitrust challenges to Hatch-Waxman settlements have done so after reviewing a full record. *See Schering-Plough*, 402 F.3d at 1058 (granting a petition for review of and reversing an agency decision made upon a full record that granted injunctive relief against certain Hatch-Waxman settlements); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F.Supp.2d 514, 517 (E.D.N.Y.2005) (granting summary judgment motion).

CONCLUSION

Because I disagree with the majority's test for judging whether a Hatch-Waxman agreement violates antitrust law, and because I believe it was inappropriate to dismiss plaintiffs' complaint without allowing discovery, I respectfully dissent.

APPENDIX E — PERTINENT TEXT OF RELEVANT STATUTES

SHERMAN ANTITRUST ACT

Section 1: Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal. Every person who shall make any contract or engage in any combination or conspiracy hereby declared to be illegal shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $100,000,000 if a corporation, or, if any other person, $1,000,000, or by imprisonment not exceeding 10 years, or by both said punishments, in the discretion of the court.

15 U.S.C. § 1.

Section 2: Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $100,000,000 if a corporation, or, if any other person, $1,000,000, or by imprisonment not exceeding 10 years, or by both said punishments, in the discretion of the court.

15 U.S.C. § 2.

Appendix E

DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT OF 1984 ("HATCH-WAXMAN ACT"), AS AMENDED

* * *

(j) Abbreviated new drug applications

(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

(2)(A) An abbreviated application for a new drug shall contain—

* * *

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section—

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) of this section for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

* * *

(B) Notice of opinion that patent is invalid or will not be infringed

(i) *Agreement to give notice.* An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give notice as required by this subparagraph.

(ii) *Timing of notice.* An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall give notice as required under this subparagraph—

(I) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(II) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

Appendix E

(iii) *Recipients of notice.* An applicant required under this subparagraph to give notice shall give notice to—

(I) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(II) the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

(iv) *Contents of notice.* A notice required under this subparagraph shall—

(I) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(II) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

* * *

(5)(A) Within one hundred and eighty days of the initial receipt of an application under paragraph (2) or within such additional period as may be agreed upon by the Secretary

and the applicant, the Secretary shall approve or disapprove the application.

(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined by applying the following to each certification made under paragraph (2)(A)(vii):

(i) If the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.

(ii) If the applicant made a certification described in subclause (III) of paragraph (2)(A)(vii), the approval may be made effective on the date certified under subclause (III). (iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) of this section before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order

because either party to the action failed to reasonably cooperate in expediting the action, except that—

(I) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—(aa) the date on which the court enters judgment reflecting the decision; or (bb) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(II) if before the expiration of such period the district court decides that the patent has been infringed—

(aa) if the judgment of the district court is appealed, the approval shall be made effective on—

(AA) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(BB) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or (bb) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of Title 35;

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in subclause (I); or

(IV) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in subclause (II). In such an action, each of the parties shall reasonably cooperate in expediting the action.

(iv) *180-day exclusivity period*

(I) *Effectiveness of application.* Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.

Appendix E

(II) *Definitions.* In this paragraph:

(aa) *180-day exclusivity period.* The term "180-day exclusivity period" means the 180-day period ending on the day before the date on which an application submitted by an applicant other than a first applicant could become effective under this clause.

(bb) *First applicant.* As used in this subsection, the term "first applicant" means an applicant that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) for the drug.

(cc) *Substantially complete application.* As used in this subsection, the term "substantially complete application" means an application under this subsection that on its face is sufficiently complete to permit a substantive review and contains all the information required by paragraph (2)(A).

(dd) *Tentative approval*

(AA) *In general*

The term "tentative approval" means notification to an applicant by the Secretary that an application under this subsection meets the requirements of paragraph (2)(A), but cannot receive effective approval because the application does not meet the requirements of this subparagraph, there

is a period of exclusivity for the listed drug under subparagraph (F) or section 355a of this title, or there is a 7-year period of exclusivity for the listed drug under section 360cc of this title.

(BB) *Limitation*

A drug that is granted tentative approval by the Secretary is not an approved drug and shall not have an effective approval until the Secretary issues an approval after any necessary additional review of the application.

(C) *Civil action to obtain patent certainty*

(i) *Declaratory judgment absent infringement action*

(I) *In general*

No action may be brought under section 2201 of Title 28, by an applicant under paragraph (2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (B)(iii) unless—

(aa) the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of such period; and

(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

(II) *Filing of civil action*

If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of Title 28, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(III) *Offer of confidential access to application*

For purposes of subclause (I)(cc), the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant under paragraph (2) for the purpose of determining whether an action referred to in subparagraph (B)(iii) should be brought. The document providing the offer of confidential access shall contain such restrictions as to

persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

(ii) *Counterclaim to infringement action*

(I) *In general*

If an owner of the patent or the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent

information submitted by the holder under subsection (b) or (c) of this section on the ground that the patent does not claim either—

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

(II) *No independent cause of action*

Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

(iii) *No damages.* An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).

(D) *Forfeiture of 180-day exclusivity period*

(i) *Definition of forfeiture event.* In this subparagraph, the term "forfeiture event", with respect to an application under this subsection, means the occurrence of any of the following:

(I) *Failure to market.* The first applicant fails to market the drug by the later of—

(aa) the earlier of the date that is—

(AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or

(BB) 30 months after the date of submission of the application of the first applicant; or

(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:

(AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.

(BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.

(CC) The patent information submitted under subsection (b) or (c) of this section is withdrawn by the holder of the application approved under subsection (b) of this section.

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(II) *Withdrawal of application.* The first applicant withdraws the application or the Secretary considers the application to have been withdrawn as a result of a determination by the Secretary that the application does not meet the requirements for approval under paragraph (4).

(III) *Amendment of certification.* The first applicant amends or withdraws the certification for all of the patents with respect to which that applicant submitted a certification qualifying the applicant for the 180-day exclusivity period.

(IV) *Failure to obtain tentative approval.* The first applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed.

(V) *Agreement with another applicant, the listed drug application holder, or a patent owner.* The first applicant enters into an agreement with another applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the agreement has violated the antitrust laws (as defined in section 12 of Title 15, except that the term includes section 45 of Title 15 to the extent that that section applies to unfair methods of competition).

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(VI) *Expiration of all patents.* All of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired.

(ii) *Forfeiture.* The 180-day exclusivity period described in subparagraph (B)(iv) shall be forfeited by a first applicant if a forfeiture event occurs with respect to that first applicant.

(iii) *Subsequent applicant.* If all first applicants forfeit the 180-day exclusivity period under clause (ii)—

(I) approval of any application containing a certification described in paragraph (2)(A)(vii)(IV) shall be made effective in accordance with subparagraph (B)(iii); and

(II) no applicant shall be eligible for a 180-day exclusivity period.

(E) If the Secretary decides to disapprove an application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

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(F)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of ten years from the date of the approval of the application under subsection (b) of this section.

(ii) If an application submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, is approved after September 24, 1984, no application may be submitted under this subsection which refers to the drug for which the subsection (b) application was submitted before the expiration of five years from the date of the approval of the application under subsection (b) of this section, except that such an application may be submitted under this subsection after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in subclause (IV) of paragraph (2)(A)(vii). The approval of such an application shall be made effective in accordance with subparagraph (B) except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the

thirty-month period referred to in subparagraph (B)(iii) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b) of this section, is approved after September 24, 1984, and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under this subsection for the conditions of approval of such drug in the subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) of this section for such drug.

(iv) If a supplement to an application approved under subsection (b) of this section is approved after September 24, 1984, and the supplement contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under this subsection for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b) of this section.

(v) If an application (or supplement to an application) submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted or which refers to a change approved in a supplement to the subsection (b) application effective before the expiration of two years from September 24, 1984.

* * *

21 U.S.C. §355(j).

(June 25, 1938, c. 675, § 505, 52 Stat. 1052; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2422, 54 Stat. 1237; June 25, 1948, c. 646, § 32(b), 62 Stat. 991; May 24, 1949, c. 139, § 127, 63 Stat. 107; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; June 11, 1960, Pub.L. 86-507, § 1(18), 74 Stat. 201; Oct. 10, 1962, Pub.L. 87- 781, Title I, §§ 102(b) to (d), 103(a), (b), 104(a) to (d)(2), 76 Stat. 781- 783, 784, 785; Aug. 16, 1972, Pub.L. 92-387, § 4(d), 86 Stat. 562; Sept. 24, 1984, Pub.L. 98-417, Title I, §§ 101, 102(a) to (b)(5), 103, 104, 98 Stat. 1585, 1592, 1593, 1597; May 13, 1992, Pub.L. 102-282, § 5, 106 Stat. 161; Aug. 13, 1993, Pub.L. 103-80, § 3(n), 107 Stat. 777; Nov. 21, 1997, Pub.L. 105-115, Title I, §§ 115(a), (b), 117, 119, 120, 124(a), 111 Stat. 2313, 2315, 2316, 2318, 2324; Nov. 29, 1999, Pub.L. 106-113, Div. B, § 1000(a)(9)

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[Title IV, § 4732(b)(11)], 113 Stat. 1536, 1501A-584; Jan. 4, 2002, Pub.L. 107-109, § 15(c)(1), 115 Stat. 1420; Dec. 3, 2003, Pub.L. 108-155, § 2(b)(1), 117 Stat. 1941; Dec. 8, 2003, Pub.L. 108-173, Title XI, §§ 1101(a), (b), 1102(a), 1103(a), 117 Stat. 2448, 2452, 2457, 2460.)

MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003

SEC. 1112. NOTIFICATION OF AGREEMENTS.

(a) AGREEMENT WITH BRAND NAME DRUG COMPANY.—

(1) REQUIREMENT.—A generic drug applicant that has submitted an ANDA containing a certification under section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act and a brand name drug company that enter into an agreement described in paragraph (2) shall each file the agreement in accordance with subsection (c). The agreement shall be filed prior to the date of the first commercial marketing of the generic drug that is the subject of the ANDA.

(2) SUBJECT MATTER OF AGREEMENT.—An agreement described in this paragraph between a generic drug applicant and a brand name drug company is an agreement regarding—

(A) the manufacture, marketing or sale of the brand name drug that is the listed drug in the ANDA involved;

(B) the manufacture, marketing, or sale of the generic drug for which the ANDA was submitted; or

(C) the 180-day period referred to in section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act as it applies to such ANDA or to any other ANDA based on the same brand name drug.

(b) AGREEMENT WITH ANOTHER GENERIC DRUG APPLICANT.—

(1) REQUIREMENT.—A generic drug applicant that has submitted an ANDA containing a certification under section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act with respect to a listed drug and another generic drug applicant that has submitted an ANDA containing such a certification for the same listed drug shall each file the agreement in accordance with subsection (c). The agreement shall be filed prior to the date of the first commercial marketing of either of the generic drugs for which such ANDAs were submitted.

(2) SUBJECT MATTER OF AGREEMENT.—An agreement described in this paragraph between two generic drug applicants is an agreement regarding the 180-day period referred to in section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act as it applies to the ANDAs with which the agreement is concerned.

(c) FILING—

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(1) AGREEMENT.—The parties that are required in subsection (a) or (b) to file an agreement in accordance with this subsection shall file with the Assistant Attorney General and the Commission the text of any such agreement, except that such parties are not required to file an agreement that solely concerns

(A) purchase orders for raw material supplies;

(B) equipment and facility contracts;

(C) employment or consulting contracts; or

(D) packaging and labeling contracts.

(2) OTHER AGREEMENTS.—The parties that are required in subsection (a) or (b) to file an agreement in accordance with this subsection shall file with the Assistant Attorney General and the Commission the text of any agreements between the parties that are not described in such subsections and are contingent upon, provide a contingent condition for, or are otherwise related to an agreement that is required in subsection (a) or (b) to be filed in accordance with this subsection.

(3) DESCRIPTION.—In the event that any agreement required in subsection (a) or (b) to be filed in accordance with this subsection has not been reduced to text, each of the parties involved shall file written descriptions of such agreement that are sufficient to disclose all the terms and conditions of the agreement.

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Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, §§ 1101-1104, 1111-1118, 117 Stat. 2066, 2448-2464 (2003).

(2)

No. 06-830

Supreme Court, U.S.
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IN THE

Supreme Court of the United States

BETTY JOBLOVE, *et al.*,
Petitioners,

v.

BARR LABORATORIES, INC., *et al.*,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Second Circuit

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BRIEF IN OPPOSITION

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QUESTION PRESENTED

Whether the Sherman Act prohibits a settlement of drug patent litigation that includes a payment to the alleged infringer and an agreement by the alleged infringer not to manufacture the patented drug in exchange for a supply of the drug and the right to sell it in competition with the patent holder, where there is no allegation that the settlement was not a resolution of a legitimate patent dispute or that the agreement exceeded the bounds of the exclusivity conferred by the patent.

STATEMENT PURSUANT TO SUPREME COURT RULE 29.6

The parent corporation of respondent Barr Laboratories, Inc. is Barr Pharmaceuticals, Inc., which is the only publicly held company that owns 10% or more of Barr Laboratories, Inc.'s stock.

Respondent AstraZeneca PLC has no parent corporation, and there is no publicly held company that owns 10% or more of its stock.

The parent corporation of respondent Zeneca Inc. is Zeneca Holdings Inc., and its ultimate parent corporation is respondent AstraZeneca PLC. Apart from respondent AstraZeneca PLC (through its indirect holding), there is no publicly held company that owns 10% or more of the stock of Zeneca Inc. or Zeneca Holdings Inc.

Respondent AstraZeneca Pharmaceuticals LP is a limited partnership whose general partner is AstraZeneca AB. The ultimate parent corporation of AstraZeneca AB is respondent AstraZeneca PLC. Apart from respondent AstraZeneca PLC (through its indirect holding), there is no publicly held company that owns 10% or more of the stock of AstraZeneca AB or that has any ownership interest in AstraZeneca Pharmaceuticals LP.

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IN THE

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BETTY JOBLOVE, *et al.*,
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On Petition for Writ of Certiorari to the United States Court of Appeals for the Second Circuit

BRIEF IN OPPOSITION

None of the reasons advanced by petitioners supports this Court's review of the court of appeals' decision. There is no conflict in the courts of appeals as to when settlements of genuine patent disputes may violate the Sherman Act. Indeed, within the past year, the Solicitor General concluded that no conflict exists that would warrant this Court's review of this issue, based on the same body of case law that exists today. *See* Brief for the United States as Amicus Curiae at 16-20, *FTC v. Schering-Plough Corp.*, 126 S. Ct. 2929 (2006) (No. 05-273) ("U.S. *Schering* Br.") ("There Is No Circuit Split Justifying This Court's Review"). Nor is there any "uncertainty," much less "confusion," Pet. 15-17, about the propriety of settling lawsuits over drug patents on terms that include consideration to generic drug manufacturers.

The court of appeals rightly rejected petitioners' contention that respondents violated the Sherman Act by settling, instead of litigating to the end, a legitimate dispute between them over the validity of the patent for the drug tamoxifen. That ruling is entirely consistent with this Court's precedents. "Where there are legitimately conflicting [patent] claims * * *, a settlement by agreement, rather than litigation, is not precluded by the [Sherman] Act," *Standard Oil Co. v. United States*, 283 U.S. 163, 171 (1931), provided that such agreements do not constrain trade beyond "the limits of the patent monopoly," *United States v. Singer Mfg. Co.*, 374 U.S. 174, 196-97 (1963). Following those principles, the court below correctly held that petitioners had failed to state a claim that respondents' settlement violated the Sherman Act, because petitioners had alleged no facts that, if proved true, would establish that the defense of the patent (and, by extension, the settlement) was not legitimate or that the settlement's terms extended beyond the scope of the patent. The petition provides no reason to question the correctness of that decision. Dismissal of the complaint was appropriate on the facts alleged, and this case accordingly provides no basis to consider "under what circumstances" a settlement might violate the Sherman Act, *cf.* Pet. *i.*

The Second Circuit properly concluded that the legality of respondents' settlement under the Sherman Act does not turn on post-hoc conjectures that, but for the settlement, respondents' patent lawsuit would have resulted in the invalidation of the patent. The court rightly reasoned that, if petitioners' arguments were accepted, virtually every settlement of patent litigation would potentially give rise to an antitrust claim—with liability hinging on the same uncertain patent question that the settlement sought to compromise, but now with the threat of trebled damages to third parties. The court also correctly decided, along with other courts, that the payment of consideration to settle a patent challenge, by itself, is not inherently improper (as petitioners conceded below, Pet. App.

36a), nor even indicative of a weak patent, *id.* at 47a, as the Solicitor General has also noted, U.S. *Schering* Br. at 10 (explaining that, in drug patent cases, such "payments are more likely, even when the patentee's legal claims are strong"). Petitioners' novel arguments find no support in this Court's antitrust or patent precedents, and it is altogether unsurprising that they were rejected by the courts below.

Apart from these considerations, this case is a poor vehicle for considering the requirements for pleading that a drug patent settlement violated the Sherman Act. As the court below noted, the "particular factual circumstances" of this case "are unlikely to recur." Pet. App. 2a. Appellate panels will no longer vacate a district court judgment as part of a settlement, as happened here. Moreover, respondent AstraZeneca successfully defended its patent in two fully litigated actions after the challenged settlement, a case-specific feature of this lawsuit that the petition all but ignores. In addition, the statutory regime that governs drug patent challenges, which the petition discusses at length, Pet. 2-3, 24-27, has been amended since respondents' settlement in 1993. And finally, the only live controversy at this point is whether petitioners have stated valid state law claims, although those state law claims presumably are governed by the same standards that govern claims under the Sherman Act, including federal patent law principles. As indirect purchasers, petitioners sought only declaratory and injunctive relief under the Sherman Act, which they can no longer obtain because respondents' agreement terminated with the expiration of the patent in 2002. These considerations all weigh against review of this case.

STATEMENT

1. In 1985, respondent AstraZeneca obtained a patent for the cancer drug tamoxifen ("the '516 patent"). Also that year, the Food and Drug Administration approved AstraZeneca's New Drug Application to begin selling the drug. Four

months later, respondent Barr Laboratories, Inc. ("Barr") filed an Abbreviated New Drug Application ("ANDA") seeking FDA approval to market a generic version of tamoxifen upon the expiration of AstraZeneca's patent.[1]

In 1987, Barr amended its ANDA to include a certification that AstraZeneca's '516 patent "[wa]s invalid or w[ould] not be infringed" by Barr's generic drug. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (1988). At the time, the filer of such a certification (a "paragraph IV certification") was entitled under the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. § 355 *et seq.*) (the "Hatch-Waxman Act"), to a 180-day period of market exclusivity for its generic drug, running from the date it began to market its drug or, if earlier, the date a court declared the patent invalid or not infringed by the drug. 21 U.S.C. § 355(j)(4)(B)(iv) (1988) (amended 1997 and 2003). The filing of a paragraph IV certification is a technical act of infringement, 35 U.S.C. § 271(e)(2)(A), and the filing of an infringement action by the patent holder within a specific period of time automatically stays the FDA from approving the filer's ANDA for thirty months, absent court action. 21 U.S.C. § 355(j)(4)(B)(iii).

In response to Barr's paragraph IV filing, AstraZeneca sued Barr for patent infringement, and Barr defended on the ground that the patent was invalid. In May 1992, after a bench trial, the district court ruled that the '516 patent was invalid and unenforceable as a result of a purported failure by AstraZeneca to disclose certain mouse test data while prosecuting the patent. *Imperial Chem. Indus., PLC v. Barr Labs.*, 795 F. Supp. 619, 627 (S.D.N.Y. 1992). AstraZeneca appealed the district court's ruling to the Federal Circuit.

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[1] Respondents AstraZeneca PLC, AstraZeneca Pharmaceuticals LP and Zeneca Inc. are referred to herein as "AstraZeneca."

2. In March 1993, while the appeal was pending, respondents settled the case. Barr surrendered its claims that the '516 patent was invalid in exchange for the right to begin selling a competing tamoxifen product under a distributorship agreement with AstraZeneca, well prior to the expiration of the patent. Barr also received a $21 million payment, and AstraZeneca also agreed to pay $45 million over ten years to Barr's intended supplier. The settlement was conditioned on the vacatur of the district court judgment and dismissal of the action. The Federal Circuit, in keeping with its practice at the time, granted respondents' joint motion for vacatur, *Imperial Chem. Indus., PLC v. Heumann Pharma GmbH*, 991 F.2d 811 (table), 1993 WL 118931, at *1 (1993), and after remand the district court dismissed the case. Barr thereafter began to sell its competing tamoxifen product.

3. After settling the lawsuit, AstraZeneca successfully defended its '516 patent against other generic drug manufacturers. In 1994, Novopharm Ltd. filed a paragraph IV certification challenging the '516 patent, and AstraZeneca sued for infringement. After trial on the merits, a federal district court in Maryland upheld the validity of the '516 patent, expressly rejecting the arguments for invalidity that had been accepted by the district court in the *Barr* case. *See* Tr. of Oral Op., *Zeneca Ltd. v. Novopharm Ltd.*, Civ. No. HAR 93-1627, at 1658-62, 1680-82 (D. Md. Apr. 26, 1996). The court's judgment was affirmed by the Federal Circuit. *Zeneca Ltd. v. Novopharm Ltd.*, 111 F.3d 144 (table), 1997 WL 168318 (1997).

In 1996, AstraZeneca brought separate infringement lawsuits against Mylan Pharmaceuticals and Pharmachemie B.V., after they each filed paragraph IV certifications. In the lawsuit against Pharmachemie, a federal district court in Massachusetts specifically rejected an argument by Pharmachemie that respondents' settlement of the *Barr* lawsuit had been improper, *see Zeneca Ltd. v. Pharmachemie B.V.*, 37 F.

Supp. 2d 85, 86, 93 (D. Mass. 1999), and after trial entered judgment for AstraZeneca on the validity of the '516 patent, *Zeneca Ltd. v. Pharmachemie B.V.*, Civ. No. 96-12413-RCL (D. Mass. Sept. 14, 2000). That judgment was not appealed. Shortly thereafter, Mylan abandoned its challenge and consented to an order that prevented it from marketing generic tamoxifen until after the expiration of the '516 patent. *See AstraZeneca UK Ltd v. Mylan Pharms., Inc.*, Civ. Nos. 00-2239, 96-335 (W.D. Pa. Nov. 30, 2000).

4. Petitioners are persons who allegedly indirectly purchased or paid for tamoxifen. Beginning in 2000, they filed thirty purported class actions in federal and state courts across the country, which were consolidated for pretrial proceedings in the federal district court for the Eastern District of New York. *In re Tamoxifen Citrate Antitrust Litig.*, 196 F. Supp. 2d 1371 (J.P.M.L. 2001). Following the district court's denial of certain petitioners' motions to remand, all petitioners were joined as plaintiffs in a single consolidated action seeking declaratory and injunctive relief under the Sherman and Clayton Acts, 15 U.S.C. §§ 1, 2, 26, and monetary remedies under state common law and various state antitrust, unfair competition and consumer protection statutes.

The complaint alleged that petitioners had paid excessive prices for tamoxifen as a result of respondents' settlement. Petitioners alleged that the benefits to Barr under the settlement exceeded the profits Barr would have earned selling generic tamoxifen had it prevailed in the lawsuit. Compl. ¶ 45. Petitioners asserted that, had the *Barr* lawsuit not been settled, "the Federal Circuit and/or the Supreme Court" would have affirmed the district court's judgment that the patent was invalid, *id.* ¶ 54, an outcome that supposedly would have

invited open competition by generic manufacturers and resulted in lower tamoxifen prices, *id.*[2]

The district court dismissed the complaint. Reviewing this Court's precedents, it observed that parties may settle patent litigation so long as they do not combine in bad faith against other competitors, Pet. App. 83a-84a, and held that petitioners had alleged no basis for inferring that respondents' settlement had been made in bad faith, *id.* at 97a-98a. The court also held that the loss claimed by petitioners was not compensable "antitrust injury," because the lack of additional generic competition was attributable, not to the settlement, but to the generic manufacturers' failures to prove that the '516 patent was invalid. *Id.* at 98a-102a.

5. The court of appeals affirmed. As an initial matter, it denied respondents' motion to transfer the case to the Federal Circuit, which under 28 U.S.C. § 1295(a)(1) has exclusive jurisdiction over appeals of cases that "arise under" federal patent law. The court noted that under *Christianson v. Colt Industries Operating Corp.*, 486 U.S. 800, 807 (1988), a case does not "arise under" patent law "as long as there is at least one alternative theory supporting the claim that does not rely on patent law." Pet. App. 23a. Applying that principle, the court concluded that the Federal Circuit did not have exclusive jurisdiction over the appeal. *Id.* at 24a.

On the merits, the court of appeals held that petitioners had failed to state an antitrust claim. The court noted that the settlement of "legitimately conflicting [patent] claims * * * is not precluded by the [Sherman] Act." *Id.* at 30a (quoting *Standard Oil*, 283 U.S. at 171). The allegation that respondents settled their lawsuit after the district court had declared

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[2] The complaint also asserted that respondents agreed "to preserve Barr's claim to the [180-day] exclusivity period so that it could be strategically deployed * * * to block any potential competitor from the market." *Id.* ¶ 57.

the patent invalid was, it held, insufficient to state an antitrust claim. *Id.* at 35a. The court denied that it could "guess with any degree of assurance what the Federal Circuit would have done" in the appeal, *id.* at 32a, noting in particular AstraZeneca's later successes defending the patent, *id.* at 34a.

The court also held that petitioners did not state a claim by alleging that the consideration paid to Barr under the settlement exceeded the supposed profits Barr would have made selling generic tamoxifen had it won on appeal. *Id.* at 36a. The court noted that, in litigation under the Hatch-Waxman regime, generic manufacturers "might well have the whip hand" in extracting substantial payments from patent holders, even when the patent holder is confident in the strength of its patent. *Id.* at 45a. To state a claim that a settlement of patent litigation violated the Sherman Act, the court held, a plaintiff must allege that "the exclusionary effects of the agreement exceeded the scope of the patent's protection," or that the patent had been obtained by fraud, or that the defense of the patent had been "objectively baseless." *Id.* at 51a-52a (citations and internal quotations omitted).

The court noted that petitioners had not alleged fraud or asserted that AstraZeneca's defense of the patent was baseless, *id.* at 52a-53a, and it held that the complaint did not support a claim that the settlement exceeded the scope of the patent, in contrast to the agreement criticized by the Sixth Circuit in *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896 (2003), *cert. denied*, 543 U.S. 939 (2004), *see* Pet. App. 54a. Nor did respondents' settlement prevent other generic manufacturers from obtaining FDA approval for their competing drugs, unlike certain "interim" agreements in other cases that did not resolve the litigation but instead "prolonged it by providing incentives to the defendant generic manufacturers not to pursue the litigation avidly." *Id.* at 55a-56a (distinguishing *Cardizem*, 332 F.3d at 907, and *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1300 (11th

Cir. 2003), *cert. denied*, 543 U.S. 939 (2004)). The court also noted that, by licensing Barr to distribute a competing tamoxifen product at a reduced price, the settlement introduced competition that would not have existed had AstraZeneca prevailed on appeal. *See id.* at 57a-58a.[3]

The dissenting judge argued that the validity of drug patent settlements should turn on their "reasonableness" in view of "the strength of the patent" at the time of the settlement, the amount of the payment to the generic challenger, the amount the generic challenger would have earned during the Hatch-Waxman exclusivity period and any ancillary anticompetitive effects of the agreement. *Id.* at 126a.

REASONS FOR DENYING THE PETITION

The petition advances no reason that warrants review of the decision below. There is no conflict in the courts of appeals, and the Second Circuit properly applied this Court's precedents in rejecting petitioners' novel antitrust claims. In addition, there are several reasons why this case, with its factual background that is unlikely ever to recur, is a poor vehicle for considering the standards for pleading that a drug patent settlement violated the Sherman Act.

I. THERE IS NO CONFLICT IN THE COURTS OF APPEALS

There is no conflict in the decisions of the circuit courts that have assessed antitrust challenges to agreements arising from drug patent litigation under the Hatch-Waxman Act. None of the three circuits that petitioners assert are in conflict

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[3] The court also held that petitioners had failed to state an antitrust claim by alleging that respondents had agreed that Barr would seek to preclude competition by other generic manufacturers. Pet. App. 63a-67a. That claim, the court held, was so lacking in any alleged factual predicate as to fall outside "the realm of plausible possibilities." *Id.* at 63a.

has permitted claims to proceed where the challenged agreements did not exceed the scope of the patents at issue. Nor has any of the three circuits considered the amount of the payment made to the generic challenger as a sufficient basis in itself for Sherman Act liability. Any variance in outcomes in the courts of appeals' decisions is attributable, not to their having adopted conflicting approaches, but to the different settlement terms under examination. In short, the conflicts claimed by petitioners do not exist. Indeed, less than a year ago, the Solicitor General explained to this Court, in a case raising similar issues, that "There Is No Circuit Split Justifying This Court's Review." Brief for the United States as Amicus Curiae at 16-20, *FTC v. Schering-Plough Corp.*, 126 S. Ct. 2929 (2006) (No. 05-273) ("U.S. *Schering* Br."). That view was based on the same body of appellate case law as exists today, including the decision by the Second Circuit below.

There is no conflict between the Second Circuit's decision below and the Sixth Circuit's decision in *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896 (2003), *cert. denied*, 543 U.S. 939 (2004), as the Solicitor General has previously noted, *see* U.S. *Schering* Br. at 19 (stating that the decision in this case "does not create any split with the Sixth Circuit's *Cardizem* decision"). In *Cardizem*, the Sixth Circuit held that an "interim" agreement, under which the patent holder paid a generic competitor not to sell a competing drug until a final resolution of patent litigation, constituted a "naked, horizontal restraint of trade" that was per se unlawful. 332 F.3d at 911. But the agreement in *Cardizem* extended to drugs "not at issue in the pending litigation," including "noninfringing" versions of the patented drug. *Id.* at 908 n.13 (citations and internal quotations omitted). In other words, it "involved payments to exclude drugs that did *not* fall within the scope of the patent alleged to be infringed." U.S. *Schering* Br. at 17 (emphasis in original).

The Second Circuit rightly distinguished respondents' settlement from the agreement in *Cardizem*. It noted that respondents' settlement, "unlike the agreement * * * in *Cardizem*," did not "restrain[] the introduction or marketing of unrelated or non-infringing products." Pet. App. 53a-54a. Nothing in the Second Circuit's decision suggests any disagreement with the Sixth Circuit's conclusion in *Cardizem*. Indeed, the Second Circuit made clear that it regarded the *Cardizem* agreement as precisely the kind of arrangement that *would* violate the Sherman Act. *Id.* at 53a-55a.[4]

Nor is there any conflict between *Cardizem* and the Eleventh Circuit's decision in *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294 (2003), *cert. denied*, 543 U.S. 939 (2004). In *Valley Drug*, the Eleventh Circuit reversed a district court ruling that certain "interim" reverse payment agreements were per se antitrust violations. The Eleventh Circuit held that antitrust liability could not be imposed on the basis that the patent was later invalidated, *id.* at 1306-07, or that the patent holder had made payments to the challenger, *id.* at 1309-11. The legality of the agreement, the court held, turned on whether its exclusionary effects "are within the scope of the exclusionary potential of the patent." *Id.* at 1311. The court in *Valley Drug* therefore remanded for the district court to determine the scope of "the protection afforded by the patents and the relevant law" and to consider "the extent to which the [a]greements reflect a reasonable implementation of the[m]." *Id.* at 1312. Any agreement outside the scope of the patent, it held, would be subject to the

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[4] The Second Circuit also noted that the *Cardizem* agreement was designed to block other potential generic competitors from coming to market, in part by delaying the resolution of the parties' patent litigation. *Id.* at 56a; *see also Cardizem*, 332 F.3d at 907-08 & n.12. Here, by contrast, as the Second Circuit noted, respondents' agreement did not constrain third parties. *Id.* at 55a-56a.

standard antitrust analysis applicable to agreements between competitors. *Id.*

That holding is entirely consistent with *Cardizem* and with the Second Circuit's decision in this case. Under *Valley Drug*, applying standard antitrust principles, a horizontal restraint on competition that exceeded the scope of the patent would be illegal, *see* 344 F.3d at 1312-13, just as it was in *Cardizem*. And in the decision below, the Second Circuit expressly approved the Eleventh Circuit's analysis in *Valley Drug* and its later decision applying the same standard in *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (2005), *cert. denied*, 126 S. Ct. 2929 (2006). Indeed, the Second Circuit's core holding—that "the question is whether the 'exclusionary effects of the agreement' exceed the 'scope of the patent's protection'"—is adopted from the Eleventh Circuit's decision in *Schering-Plough*. Pet. App. 53a (quoting 402 F.3d at 1076); *see also* U.S. *Schering* Br. at 19 (noting the Second Circuit's endorsement of the Eleventh Circuit's approach).[5]

Nor do the Second Circuit and the Eleventh Circuit have conflicting views on the significance of the amount of consideration paid to generic manufacturers in settling patent disputes. Nothing in the decision below conflicts with *Valley Drug*'s observation that large payments "might be evidence supporting a claim that the patentee knew that the patent was procured by fraud, or knew that the patent was invalid, or that

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[5] Although the *Valley Drug* court read *Cardizem* as suggesting that even agreements not to market infringing products might be per se illegal, it also recognized that such a rule was not necessary to the decision in *Cardizem*, since the agreement there exceeded the scope of the patent. *See Valley Drug*, 344 F.3d at 1311 n.26. As the Solicitor General has noted, "it is far from clear that the per se rule employed [in *Cardizem*] extends beyond the unique circumstances of that case." U.S. *Schering* Br. at 17; *see also* Brief for the United States as Amicus Curiae at 11, *Andrx Pharms., Inc. v. Kroger Co.*, 543 U.S. 939 (2004) (No. 03-779) (stating that *Cardizem* and *Valley Drug* "do not present a square conflict").

there was no objective basis to believe the patent was valid." 344 F.3d at 1310 n.22; *cf.* Pet. 13-14. The Second Circuit never suggested that the size of a payment would be irrelevant to showing fraud or bad faith. It held, rather, that an allegation of a large payment was not in itself sufficient to state a claim that a patent enforcement action was brought and settled in bad faith. *See* Pet. App. 36a-48a. The Eleventh Circuit reached the same basic conclusion in *Valley Drug*. It could not conclude, it held, "merely from the size of the payments, that there were no genuine disputes over the validity of the patent." 344 F.3d at 1310. Rather, it tied the significance of large payments to the presence of fraud, bad faith or objective unreasonableness, *id.* at 1310 n.22, the same elements that the Second Circuit stated would support a Sherman Act claim, Pet. App. 51a-52a. On these points, as otherwise, the two circuits agree. There is no conflict to be resolved by this Court.[6]

II. THE COURT OF APPEALS CORRECTLY HELD THAT PLAINTIFFS' ALLEGATIONS FAILED TO STATE A CLAIM UNDER THE SHERMAN ACT

The Second Circuit correctly rejected petitioners' novel theory that respondents' settlement was unlawful because it brought to an end litigation that purportedly would have

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[6] Petitioners incorrectly argue that *Valley Drug* would have treated respondents' agreement as per se illegal because it was reached after a judgment that the patent was invalid, citing *Valley Drug*'s statement that it was not per se unlawful for generic manufacturers to agree not to sell infringing products at a time when "no court had declared [the] patent invalid." Pet. 13 (quoting 344 F.3d at 1306 & n.18). That statement does not necessarily imply that it *would* be unlawful to reach such an agreement while a district court judgment of invalidity is being appealed. Moreover, even if it did, the possibility of a disagreement between the courts of appeals on that narrow point would not merit review, because it is unlikely that future cases will feature settlements made after a district court judgment of invalidity. *See infra* at 26-27.

resulted in the invalidation of the '516 patent. It also correctly determined that petitioners had not stated a claim simply by alleging that the settlement payments to Barr exceeded the profits that Barr allegedly would have earned selling generic tamoxifen. The Second Circuit's analysis of these issues was entirely consistent with established principles of patent and antitrust law, and none of the arguments advanced by petitioners justifies its review by this Court.

A. Agreements To Settle Legitimate Patent Disputes Do Not Violate the Sherman Act

There is no question that "[w]here there are legitimately conflicting [patent] claims * * *, a settlement by agreement, rather than litigation, is not precluded by the [Sherman] Act." *Standard Oil Co. v. United States*, 283 U.S. 163, 171 (1931). Settlements of patent disputes serve the basic purposes of patent law by resolving costly litigation that might otherwise discourage innovation. Pet. App. 30a-31a; *see also Flex-Foot, Inc. v. CRP, Inc.*, 238 F.3d 1362, 1369 (Fed. Cir. 2001) ("[S]ettlement of [patent] litigation is * * * strongly favored by the law."). Nor is there anything about settlements of drug patent disputes that would alter this general principle. Petitioners do not contend that all drug patent settlements, or even all so-called "reverse payment" settlements, are unlawful. Pet. App. 36a, 41a.

It is also well established that "the essence of a patent grant is the right to exclude others from profiting by the patented invention." *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980). For this reason, it has long been recognized that a patent holder, in granting a license, may enter into agreements restricting competition in the patented product that might be unlawful under the Sherman Act absent the statutory right against infringement that the patent confers. *See, e.g., Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 135-36 (1969); *Ethyl Gasoline Corp. v. United States*, 309 U.S. 436, 455-56 (1940); *Gen. Talking Pictures*

Corp. v. Western Elec. Co., 304 U.S. 175, 181 (1938); *see also Simpson v. Union Oil Co.*, 377 U.S. 13, 24 (1964) ("The patent laws * * * are *in pari materia* with the antitrust laws and modify them *pro tanto*."). Such an agreement, without more, does not raise antitrust concerns unless it has the effect of restraining trade or erecting barriers to entry beyond the scope of the patent. *See, e.g., United States v. Line Material Co.*, 333 U.S. 287, 308 (1948); *United States v. Masonite Corp.*, 316 U.S. 265, 278-79 (1942). Nor do petitioners seek review of the court of appeals' case-specific determination that respondents' settlement did not exceed the scope of the '516 patent. *See* Pet. App. 53a-59a.

Where, as here, an agreement falls within the scope of a patent, a claim that the agreement violated the Sherman Act must be supported by factual allegations that the patent was obtained by fraud or had been enforced in bad faith. In *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172, 175-77 (1965), this Court held that a party that enforces a patent knowing that it was fraudulently obtained, and thus invalid, may be sued for violating the Sherman Act. The Court's opinion made clear, however, that the essential predicate for such a claim was the allegation that the patent had been "procured by intentional fraud," not that the patent was later held to be invalid. *Id.* at 176; *see also id.* at 177 (stating that the patent holder's "good faith would furnish a complete defense"). In keeping with these principles, the courts of appeals have recognized that the bad faith or baseless enforcement of patents may give rise to antitrust violations. *See, e.g., Valley Drug*, 344 F.3d at 1310 n.22; *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1068-71 (Fed. Cir. 1998) (citing *Walker Process* and *Prof'l Real Estate Invs., Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49 (1993)).

The court of appeals' holding that petitioners failed to state a claim because they did not allege that the '516 patent

had been fraudulently obtained or enforced in bad faith was entirely consistent with these patent and antitrust precedents. Petitioners' assertion that the court deemed patent settlements "per se legal," Pet. 12, both mischaracterizes its ruling and ignores its precedential support in the decisions of this Court and other courts of appeals. Their argument that the court of appeals "imported" part of its standard from cases regarding protected First Amendment activity, *id.* at 19-20, fails to take account of the well established antitrust doctrines reflected in those precedents. Petitioners have cited no contrary authority of this Court (or any other court) that calls into question the court of appeals' reasoning below. [7]

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[7] Petitioners cite several cases where antitrust claims proceeded beyond the pleadings, Pet. 18, but in each of them, the factual allegations differed from those here. In *Cardizem*, 332 F.3d at 907-08 & nn.12-13, the agreement limited non-infringing products and prevented other generics from entering the market. *See also supra* at 11 n.4. Similar allegations were made in *Andrx Pharmaceuticals, Inc. v. Elan Corp., PLC*, 421 F.3d 1227, 1231, 1235 (11th Cir. 2005) (noting that agreement prevented other generics from entering the market), and in *In re Terazosin Hydrochloride Antitrust Litigation*, 352 F. Supp. 2d 1279, 1314-15 & nn.35-36 (S.D. Fla. 2005) (analogizing agreement to the one at issue in *Cardizem* and distinguishing it from the one here). In *In re Buspirone Patent Litigation*, 185 F. Supp. 2d 363, 366, 378 (S.D.N.Y. 2002), the complaint alleged that the "settlement was a sham" that the parties made in bad faith. And in *Andrx Pharmaceuticals, Inc. v. Biovail Corp. International*, 256 F.3d 799, 803-05, 810, 819 (D.C. Cir. 2001), the court addressed a claim by a competitor that it had been prevented from entering the market as a result of the same agreement at issue in *Cardizem*. Although the district court in *In re Ciprofloxacin Hydrochloride Antitrust Litigation* denied a motion to dismiss, 261 F. Supp. 2d 188, 230 (E.D.N.Y. 2003), it later granted summary judgment to the defendants once it became clear (as it was here on the face of the complaint) that the agreements had no anticompetitive effect beyond the scope of the patent, 363 F. Supp. 2d 514, 540-41 (E.D.N.Y. 2005).

B. Petitioners Have Not Stated a Sherman Act Claim by Alleging that the Patent Had Been Declared by the District Court, or Could Be Shown by Petitioners, To Be Invalid

As has been the case throughout this lawsuit, petitioners do not clearly state the theory of antitrust liability that purportedly justifies their claim. They appear to argue, at least in part, that they have stated a Sherman Act claim by alleging that respondents agreed as part of their settlement to the vacatur of the district court's decision that the '516 patent was invalid. *See, e.g.*, Pet. 4, 10-11, 20-21, 23. But insofar as they rely on that allegation, their claim rests on facts that may well be unique to this lawsuit. As discussed below, *see infra* at 26-27, appellate courts have long since ceased to vacate district court judgments on the motion of settling parties. Accordingly, even if the vacatur of the initial judgment supported petitioners' Sherman Act claims (and it does not), it would not be a useful expenditure of this Court's resources to pass on the validity of a claim that is unlikely to be asserted in any other lawsuit.[8]

In any event, on its merits, petitioners' claim suffers from the inescapably conjectural nature of its core proposition that, but for the settlement, respondents' patent dispute would ultimately have been won by Barr. The court of appeals rightly concluded that courts are poorly suited to such speculative investigations into their own workings. Pet. App. 34a (embracing "the general rule that we will ordinarily refrain from guessing what a court will hold or would have held"). That determination was unquestionably correct. How petitioners' conjectural claim would be tried to a jury, as their complaint

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[8] For the same reason, petitioners' contention that the court of appeals was wrong to ascribe a presumption of validity to the '516 patent despite the vacatur of the initial district court judgment, Pet. 20-21, also provides no basis for review.

demands, is a baffling proposition. Recognizing the complexity of patent law, Congress has provided that appeals of patent judgments lie exclusively with the Federal Circuit, 28 U.S.C. § 1295(a)(1). And yet petitioners propose to put to a jury the question of how a panel of that specialized court would have decided AstraZeneca's appeal.

Petitioners argue that little speculation would be necessary to predict the outcome of respondents' lawsuit, in view of the initial district court judgment on the patent. Pet. 10-11. But any reliance on that initial ruling would wrongly ascribe preclusive significance to a vacated judgment, as the Federal Circuit noted in affirming AstraZeneca's successful second defense of the '516 patent, *see Zeneca Ltd. v. Novopharm Ltd.*, 111 F.3d 144 (table), 1997 WL 168318, at *2 (1997). Moreover, as the court of appeals noted, any inference that might be drawn from the initial patent ruling is undermined by AstraZeneca's later successes defending the '516 patent. Pet. App. 34a & n.17. The court also correctly noted the difficulty of predicting the outcomes of appeals, as reflected in the frequency with which appeals are settled. *Id.* at 33a.[9]

Petitioners also argue the more ambitious point that, when patent litigation is settled, potentially affected third parties "should have their own opportunity to show the weaknesses of the patent." Pet. 21. Apart from being subject to the same difficulties of proof noted above, that position is also contrary to the basic rule of *Walker Process* that an assertion of patent invalidity cannot by itself support a claim under the Sherman Act. Petitioners' desire to "show the weaknesses" of the

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[9] The court also noted that in 1993 patent invalidity rulings were reversed "at a relatively high rate." *Id.* at 33a n.16. *See also Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 331 n.21 (1971) (noting that "[b]ecause of the intrinsic nature of [patent validity questions], the first [court's] decision can be quite wrong, or derived from an insufficient record or presentation") (citation and internal quotations omitted).

tamoxifen patent—i.e., to demonstrate in this lawsuit that the patent was invalid—is precisely the kind of challenge that *Walker Process* made clear would not be permitted. As Justice Harlan, in a concurring opinion, took pains to explain, "a private cause of action would *not* be made out if the plaintiff * * * showed no more than invalidity of the patent * * *." 382 U.S. at 179 (emphasis in original).

Although the federal government, like an alleged infringer or licensee defending a claim by a patent holder, may challenge the validity of a patent where the government contends that the patent was used to constrain competition outside the patent's scope, *see United States v. Glaxo Group Ltd.*, 410 U.S. 52, 58-59 (1973), petitioners cannot pursue a claim on this ground. Even the government does not have a "roving commission" to "attack a patent by basing an antitrust claim on the simple assertion that the patent is invalid." *Id.* at 59 (citing *Walker Process*, 382 U.S. 172). Petitioners cite no authority for the proposition that they have such a "roving commission" or standing to challenge the validity of a patent.

Nor can petitioners avoid the rule of *Walker Process* by arguing that their claim is directed at the settlement agreement rather than the validity of the patent. Since the agreement did not exceed the scope of the '516 patent, the only way it could have had any consequence for petitioners was by protecting an otherwise invalid patent, as petitioners themselves recognized in pleading their claim, Compl. ¶ 54, and thus petitioners' challenge to the settlement is necessarily, at bottom, an attack on the validity of the patent. The court of appeals' refusal to let that claim proceed was entirely consistent with this Court's precedents.

Petitioners invoke *Standard Oil* and the concurring opinion in *Singer* as ostensibly supporting their right "to show the weaknesses of the patent," Pet. 21 (citing the dissent below, Pet. App. 120a), but neither *Standard Oil* nor *Singer* suggests that claims of patent invalidity, alone, are enough to support

an antitrust claim. To the contrary, both decisions are entirely consistent with *Walker Process* and the decision below. In *Standard Oil*, the question of patent validity was tied to claims that the challenged agreements had been made "in bad faith" and that the parties' infringement claims were "a pretext" that had been asserted "merely as a means of lending color of legality" to the parties' agreements. 283 U.S. at 180. And in *Singer*, the parties had "collu[ded] * * * to prevent prior art from coming to or being drawn to the [Patent] Office's attention," i.e., had conspired to deceive the patent office in prosecuting their patents. 374 U.S. at 199-200 (White, J., concurring). Neither case suggests that the Sherman Act supplies a claim to a private litigant who wishes to "show the weaknesses" of a patent without also demonstrating fraud or bad faith. And here, as noted already, petitioners have not alleged that the '516 patent had been obtained by fraud, that AstraZeneca's defense of the patent was not genuine or that the settlement was made in bad faith.

The court of appeals rightly recognized that patent settlements would be greatly discouraged if antitrust plaintiffs could "show the weaknesses" of a patent after a settlement. There would be little reason to settle if the resolution of one dispute opened the patent to question by third parties in a new antitrust action, this time with the threat of trebled damages. *See* Pet. App. 30a-32a, 42a, 51a n.26. Further, as the Eleventh Circuit reasoned in *Valley Drug*, "[b]y restricting settlement options, which would effectively increase the cost of patent enforcement, the proposed rule would impair the incentives for disclosure and innovation." 344 F.3d at 1308. Similar considerations underlay this Court's reluctance to permit antitrust claims challenging the validity of a patent. *See Walker Process*, 382 U.S. at 179-80 (Harlan, J., concurring).

Finally, if petitioners are attempting to argue that they should be allowed to show some "weakness" in the patent short of actual invalidity, their position was raised for the first

time in their petition for rehearing below, was never discussed by the court of appeals and accordingly is not properly raised for this Court's consideration. *See Hoover v. Ronwin*, 466 U.S. 558, 574 n.25 (1984). Beyond this, petitioners have articulated no reason why the settlement of litigation challenging a weak-but-not-invalid patent is anti-competitive or should be unlawful. Nor do they describe the standard that would supposedly establish that a weak-but-not-invalid patent was "too weak" to permit settlement of a challenge to its validity. To the extent that petitioners advance such a position now, their formless claim provides no basis for granting the petition.

C. Petitioners Have Not Stated a Sherman Act Claim by Alleging that the Settlement Payment to Barr Exceeded the Profits that Barr Would Have Made Selling Generic Tamoxifen

Petitioners argue that the dismissal of their claims was improper because AstraZeneca's payments to Barr under the settlement allegedly exceeded the profits that Barr would have earned selling generic tamoxifen had it prevailed in the patent litigation. Here again, the court of appeals correctly concluded, following other courts, that petitioners' allegation failed to support a Sherman Act claim, and petitioners have supplied no reason that would warrant review of that decision.

The crux of petitioners' argument is that the payment to Barr enabled AstraZeneca to insulate its patent from challenge. Petitioners do not argue that the payment demonstrates that AstraZeneca was defending the patent in bad faith or that the settlement was a pretext. Nor do they dispute the court of appeals' conclusion that under the Hatch-Waxman regime, even a patent holder confident in the strength of its patent might be prepared to make substantial payments to eliminate even a small risk of an adverse outcome. Pet. App. 43a-45a;

see also Schering-Plough, 402 F.3d at 1075; *Valley Drug*, 344 F.3d at 1309-10; U.S. *Schering* Br. at 10 (explaining that, under the Hatch-Waxman Act, payments to patent challengers "are more likely, even when the patentee's claims are strong"). Rather, petitioners argue that, because the settlement payments to Barr purportedly exceeded Barr's expected profits from selling its product, petitioners are entitled to "show the weaknesses of the patent." Pet. 21.

As already discussed, however, the Sherman Act does not authorize antitrust suits on a claim that a patent is invalid. *See supra* at 18-19. Under *Walker Process*, it makes no difference that respondents settled prior litigation testing the patent or that their settlement provided for an allegedly "excessive" payment to Barr. Only allegations of fraud or bad faith will support such a claim, and as noted, petitioners have not argued fraud or bad faith in challenging respondents' settlement.

Petitioners argue at length that payments to settle drug patent litigation are contrary to the Hatch-Waxman Act's objective of promoting challenges to drug patents. *See* Pet. 7-8, 17. But nothing in the Hatch-Waxman Act prohibits or even impedes settlement of patent litigation. Nor does it follow from the Hatch-Waxman Act's encouragement of patent litigation that patent settlements are contrary to federal policy or that consumers may challenge such settlements under the Sherman Act when they provide for payments. Notably, in 2003, at a time after the dismissal of petitioners' claims by the district court in this case, Congress required parties who settled infringement actions based on paragraph IV certifications to file copies of their settlements with the Federal Trade Commission, *see* Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("2003 Medicare Act"), Pub. L. No. 108-173, §§ 1111-18, 117 Stat. 2066 (codified at

21 U.S.C. § 355), but took no action to limit the terms of settlement.[10]

Although the point was hardly critical to the holding below, petitioners challenge the court of appeals' assessment that a settlement with the first generic manufacturer to challenge the '516 patent would prompt other generic manufacturers to challenge the patent as well. *See* Pet. 24-26 (citing Pet. App. 50a). That assessment, they argue, rested on a mistaken belief that the Hatch-Waxman Act provided incentives for other generic manufacturers to challenge the patent. The record, however, plainly bears out the court's assessment, because after Barr settled its lawsuit, three other generic manufacturers *did* file paragraph IV certifications challenging the tamoxifen patent. *See supra* at 5. Nor was the court of appeals mistaken in its understanding of the Hatch-Waxman Act as it existed at the time of the settlement.[11] But in any event, the court's assessment of the

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[10] Congress is considering legislation amending the Hatch-Waxman Act that would prohibit certain settlements of drug patent infringement suits brought pursuant to the Act. *See* S. 316, 110th Cong. § 3 (2007) (proposing to prohibit "resolv[ing] or settl[ing] a patent infringement claim" on terms that would provide the paragraph IV filer "anything of value" apart from "the right to market [its purportedly infringing product] prior to the expiration of the patent").

[11] The paragraph IV filers who challenged the tamoxifen patent after respondents settled their lawsuit clearly perceived a possibility to benefit from the statutory 180-day exclusivity period after Barr withdrew its application. *See Mylan Pharms., Inc. v. Henney*, 94 F. Supp. 2d 36, 44 (D.D.C. 2000) (noting that Mylan sought the 180-day exclusivity period after Barr withdrew its paragraph IV certification). At the time, it was possible that the statute would be construed to grant subsequent filers exclusivity in certain circumstances. *See Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1064 n.4 (D.C. Cir. 1998) (observing that "the statute might conceivably be read to confer this 180-day period on a second or third applicant in some situations"); *see also* 64 Fed. Reg. 42,873, 42,875 (Aug. 6, 1999) ("The statutory language describing which applications are eligible for 180-day generic drug exclusivity is ambiguous."). It was

incentives that existed in 1993 does not warrant review by this Court, especially given that, since 1993, the relevant statutory provisions have been amended. *See infra* at 27-28.

Petitioners assert that, at a minimum, the first settlement would delay the ultimate adjudication of the patent's validity. Pet. 24. The possibility of such delay is irrelevant, however, to whether petitioners have stated a claim under the Sherman Act. Whatever shortcomings petitioners may perceive in the Hatch-Waxman Act's design for fostering patent challenges, petitioners cannot invent a Sherman Act right for themselves to "show the weaknesses of the patent" based on the purported lack of promptness in alternative challenges.

Nor does the supposed trend identified by the FTC in favor of settlements that include consideration to the generic challenger suggest, as petitioners imply, Pet. 15-16, that patent challenges are no longer being litigated to judgment. Statistics showing that such payments have been featured more frequently since 2004, when parties were first required to file agreements settling paragraph IV litigation, say nothing about the number of patent cases being litigated to judgment. And the number of lawsuits resulting in judgments that patents are invalid or unenforceable since *Valley Drug* demonstrates that

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therefore reasonable for the Second Circuit to conclude, in the context of this case, that the subsequent challengers may have been "spurred by the additional incentive (at the time) of potentially securing the 180-day exclusivity period available upon a victory in a subsequent infringement lawsuit * * *." Pet. App. 55a-56a. Indeed, even the commentator cited by petitioners has acknowledged that the relevant statutory and regulatory provisions were susceptible to more than one interpretation at the time. *See* C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1583 & n.125 (Nov. 2006) (conceding that interpretation that only the first filer was eligible for exclusivity was "not the only plausible interpretation of the relevant statutory provision").

settlements have not foreclosed such outcomes, petitioners' alarmist claims notwithstanding.[12]

In support of review, petitioners also point to the FTC's views on drug patent settlements, Pet. 9, but those views provide no basis for reviewing the decision below. The FTC maintains that the strength of the patent is irrelevant, instead arguing that settlement payments take the place of other consideration that would tend to enhance competition, such as license agreements or agreements to permit entry on a date prior to the expiration of the patent. *See In re Schering-Plough Corp.*, No. 9297, 2003 FTC LEXIS 187, at *60-61, *76-79 (FTC Dec. 8, 2003), *rev'd*, 402 F.3d 1056 (11th Cir. 2005) (rejecting FTC's approach), *cert. denied*, 126 S. Ct. 2929 (2006). Petitioners' theory of liability, by contrast, is focused on the purported "weaknesses" in the patent itself. Moreover, the FTC stated in 2003, after the district court's dismissal of petitioners' claims below, that AstraZeneca's success in defending the patent supported the district court's ruling because it indicated that respondents' settlement did not harm consumers:

> "In [*Tamoxifen*], the validity of [AstraZeneca's] patent was the crucial issue in the underlying patent dispute and, subsequent to the settlement in question, [AstraZeneca's] patent was successfully defended in

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[12] Since *Valley Drug*, at least six drug patents challenged pursuant to the Hatch-Waxman Act have been completely or partially invalidated after review by the Federal Circuit, including patents for Paxil and Lipitor. *See Geneva Pharms., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373 (Fed. Cir. 2003); *Merck & Co., Inc. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364 (Fed. Cir.), *cert. denied*, 126 S. Ct. 488 (2005); *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331 (Fed. Cir. 2005), *cert. denied*, 126 S. Ct. 2887 (2006); *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312 (Fed. Cir. 2006); *Pfizer, Inc. v. Ranbaxy Labs. Ltd.*, 457 F.3d 1284 (Fed. Cir. 2006), *petition for cert. filed*, 75 U.S.L.W. 3403 (U.S. Jan. 22, 2007) (No. 06-1016); *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286 (Fed. Cir. 2006).

> litigation with three other generic challengers. In a private action for damages, after the fact, the *Tamoxifen* [district] court had good reason to believe that the settlement did not ultimately cause consumer harm." *Id.* at *71.

Although the FTC supported petitioners' request for rehearing below, it did not retract its endorsement of the result in this case. Given that endorsement, and that petitioners did not advance below the FTC's theory that settlement payments unlawfully substitute for more procompetitive settlement terms, the FTC's views provide no basis for reviewing the decision below.[13]

III. THIS CASE IS A POOR VEHICLE FOR DETERMINING WHEN SETTLEMENTS OF DRUG PATENT CLAIMS MAY VIOLATE THE SHERMAN ACT

Several features of this case make it a poor vehicle for considering when a patent settlement may violate the Sherman Act. To the extent that the issues presented by the petition hold any interest, this Court should defer addressing them until presented with an appropriate case.

1. Important aspects of this case are highly unusual and almost certain never to recur. Respondents settled their patent dispute after a district court had first held the patent invalid and unenforceable, and the settlement was conditioned on, and brought about, the vacatur of that judgment. This feature of the settlement, so emphasized by petitioners, *see* Pet. 4, 11, 20-21, 23, is to our knowledge absent from every other drug patent settlement that has been challenged as

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[13] Nor, for that matter, do petitioners point to any case to support the proposition that an otherwise lawful agreement or settlement violates the Sherman Act simply because the agreement did not include other terms that might have been more procompetitive.

anticompetitive. Nor is it likely to be presented in future cases, given that, shortly after the settlement here was reached in 1993, this Court in *U.S. Bancorp Mortgage Co. v. Bonner Mall Partnership*, 513 U.S. 18, 27-29 (1994), ended the practice of vacating judgments in cases settled on appeal.

This case also features the unusual circumstance that, after the initial district court ruling of invalidity was vacated, two other federal district courts (and, in one case, the Federal Circuit) later enforced the tamoxifen patent against two other generic manufacturers. This case-specific sequence of conflicting judgments, although scarcely mentioned by petitioners, was noted repeatedly by the court of appeals. *See* Pet. App. 34a, 55a-57a, 65a-67a. Nor can this pattern recur after *Bonner Mall*. With no means of obtaining vacatur, a patentee whose patent has been declared invalid would be precluded from enforcing the patent against other infringers, *see Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 331 (1971), and thus could never obtain a subsequent judgment that the patent was valid, as occurred in this case. In short, the highly unusual background of this case, which was important to the analysis of the courts below, distinguishes this action from other lawsuits challenging patent settlements. For this reason, it is highly probable that a decision in this case would have only limited application to other cases presenting less extraordinary circumstances.

2. The 180-day exclusivity provisions of the Hatch-Waxman Act that foster challenges to drug patents, which petitioners argue at length that the Second Circuit misconstrued, *see* Pet. 24-27, have been amended and clarified since respondents settled their patent dispute in 1993. (The petition reproduces the current version of the statute, *see* Pet. App. E.) Among other amendments, in 2003, Congress introduced the term "first applicant" into the statute to describe applicants who may be eligible for the 180-day exclusivity period, changed the manner in which exclusivity is triggered

and introduced mechanisms by which exclusivity may be forfeited. *See* 2003 Medicare Act, Pub. L. No. 108-173, § 1102(a), 117 Stat. 2066 (codified at 21 U.S.C. § 355(j)(5)(B)(iv), (j)(5)(D)). Neither the courts nor the FDA have definitively interpreted these new provisions, which could significantly alter the way exclusivity operates when patent litigation is settled. If the exclusivity regime bears on whether respondents' settlement violated the Sherman Act, as petitioners argue, a decision in this case, insofar as based on provisions of law that are no longer in effect, would provide only limited guidance for other cases.

3. Whether petitioners have stated a valid Sherman Act claim is relevant, at this stage of the case, only because the standards necessary for stating a claim under the Sherman Act presumably also govern petitioners' state competition and consumer protection law claims. Petitioners, as indirect purchasers, sought only declaratory and injunctive relief under the Sherman Act. That relief is no longer obtainable, because respondents' agreement terminated in 2002 with the expiration of the '516 patent. *Cf. Standard Oil*, 283 U.S. at 182 (holding that, where "the relief * * * sought is an injunction, and hence relates only to the future * * *, the alleged validity of [canceled] provisions has become moot") (internal citations omitted). Although without jurisdictional import—because petitioners have asserted damages claims under their state law causes of action—this feature of the case provides another prudential basis for denying the petition. Even though petitioners' state law claims are presumably governed by Sherman Act standards, and are necessarily subject to limits imposed by federal patent law, the Court's examination of claims that a settlement of drug patent litigation violated the Sherman Act would most appropriately be conducted in a case presenting a live Sherman Act claim.

CONCLUSION

For the reasons set forth above, the petition for a writ of certiorari should be denied.

Respectfully submitted,

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FEBRUARY 2007

(8)

No. 06-830

IN THE

Supreme Court of the United States

In Re: TAMOXIFEN CITRATE ANTITRUST LITIGATION

JOBLOVE, ALLIED SERVS., DIV WELFARE FUND, BENNISH, KOONAN, GREAT LAKES HEALTH PLAN INC., LACAVA, DONEGA, SMITH, LOVINGER, WOOLLACOTT, WHITESIDE, PLATT, UNDERWOOD, TEAMSTERS LOCAL 237, LYNCH, CALLAWAY, MALONEY, MECHANICAL CONTRACT, IBEW-NECA LOCAL 505 HEALTH & WELFARE PLAN, A.F. OF L. – A.G.C. BUILDING TRADES WELFARE FUND, SHEET METAL WORKERS LOCAL 441 HEALTH & WELFARE PLAN, LOCAL 1199 NAT'L BENEFIT FUND FOR HEALTH AND HUMAN SERVICES, NEW YORK STATEWIDE SENIOR ACTION COUNCIL, MARKS, BLONSTEIN,

Petitioners,

v.

BARR LABS., INC., ASTRAZENCA PHARMACEUTICALS LP, ZENECA INC., ASTRAZENECA PLC,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

SUPPLEMENTAL BRIEF FOR PETITIONERS

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This supplemental brief is filed pursuant to Rule 15.8 of the Rules of this Court, to address arguments made by the United States in its brief as amicus curiae ("U.S. Br."). The United States agrees that the Court of Appeals' decision below applies the wrong standard and conflicts with the Eleventh Circuit's decision in *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006), and that the question of law at issue is important and should be settled by this Court, thereby satisfying the criteria of Rule 10(a) and (c). Nonetheless, the United States recommends that the Court deny certiorari — thereby allowing pervasive uncertainties affecting the $200 billion prescription drug industry to persist — until some unidentified, more "attractive vehicle," arising in the post-2003 regulatory context, wends its way to the Court.

As shown in the Argument below, the United States' analysis overlooks multiple points that show this case is, in fact, a compelling one for certiorari. In summary:

A. Federal law issues are not "moot" here, for three reasons:

1. An injunction can properly enjoin a repeated antitrust wrongdoer from engaging in similar unlawful practices, so that as a matter of law, Petitioners' injunctive claim under federal law is not "moot." *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 133 (1969);

2. The effect of a federal patent on a state law antitrust claim for damages raises a question of federal defense, as to which certiorari is just as appropriate as with regard to a federal affirmative claim. *Cf. Franchise Tax Board v. Construction Laborers Vacation Trust*, 463 U.S. 1, 12 n.12 (1983) (concerning federal preemption defense); and

3. The same conduct is unlawful under both state and federal antitrust law. Thus, this case falls squarely within the rule that it is appropriate for this Court to review interpretations of state law that have been "influenced by an accompanying interpretation of federal law." *Three Affiliated Tribes of Fort Berthold Reservation v. Wold Eng'g, P.C.*, 467 U.S. 138, 152 (1984).

B. Any unique aspects of this case do not affect the answer to the question presented; instead, the same broad questions of law are presented in this case as in other cases.

C. This case presents a straightforward opportunity to resolve important legal issues surrounding reverse payment agreements that will likely be more complex to resolve in connection with later agreements, which increasingly rely upon complicating mechanisms to obscure payments to the generic firm in return for delay, and thus will involve *more* "unique facts" than this case does.

ARGUMENT

A. 1. The United States notes that Petitioners sought injunctive and declaratory relief under Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, and contends that claim became moot upon the expiration of Zeneca's patent in 2002. U.S. Br. 17. One of the objectives when these actions were filed was, indeed, to enjoin Respondents' compliance with the challenged Agreements and to facilitate commercial launches of generic tamoxifen.[1] While this is now unnecessary, broader relief to prohibit Respondents (particularly Respondent Barr Laboratories) from engaging in pay-for-delay settlements may nonetheless be appropriate. As noted in the petition, Barr has been paid to delay efforts to market generic Cipro®, *see In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514 (E.D.N.Y. 2005), and generic Ovcon 35®, *see Federal Trade Commission v. Warner Chilcott Holdings, Inc.*, No. 1:05-cv-021790CKK (D.D.C.), as well as numerous other leading drugs.[2]

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1. The first constituent action in this multidistrict litigation to seek federal injunctive relief is the *Joblove* action (E.D.N.Y. No. 1:00-cv-6046), filed on October 6, 2000. *See* Pet. 5.

2. *See* C. Scott Hemphill, *Drug Patent Settlements Between Rivals: A Survey*, at 3 (Mar. 12, 2007) attached to Testimony of C. Scott Hemphill before the House Committee on Energy and Commerce, Hearing on H.R. 1902, May 2, 2007, *available at*: http://energycommerce.house.gov/cmte_mtgs/110-ctcp-hrg. 050207.Hemphill-testimony.pdf. ("Of the seventeen innovators and eighteen generic firms that are party to the

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Pet. 7-8, n. 8. Petitioners' complaint sought "such other relief as [the district court] may deem just and proper under the circumstances," C.A. App. A-58, and Petitioners (including large third-party payors who pay for most prescription drugs) have a broad interest in ensuring that cost-saving, generic pharmaceuticals are available without collusively-imposed delays.

In *Zenith*, the Court stated that "[w]e see no reason that the federal courts, in exercising the traditional equitable powers extended to them by § 16 [of the Clayton Act, 15 U.S.C. § 26], should not respond to the salutary principle that when one has been found to have committed acts in violation of a law he may be restrained from committing *other related* unlawful acts." 395 U.S. at 133 (citation omitted; emphasis added). And even before *Zenith*, courts recognized that the voluntary cessation of illegal conduct does not render claims for injunctive relief moot. *U.S. v. W. T. Grant Co.*, 345 U.S. 629, 632-33 (1953). In *W. T. Grant*, the government brought civil actions challenging interlocking corporate directorates. A director resigned from some of the posts to eliminate the interlocks, but the Court held that these steps did not moot the claim for injunctive relief.

> Both sides agree to the abstract proposition that voluntary cessation of allegedly illegal conduct does not deprive the tribunal of power to hear and determine the case, i.e., does not make the case moot. A controversy may remain to be settled in such circumstances, e.g., *a dispute over the legality of the challenged practices*. The defendant is free to return to his old ways. *This, together with a public interest in having the legality of the practices settled, militates against a mootness conclusion....*
>
> The case may nevertheless be moot if the defendant can demonstrate that there is *no*

(Cont'd)

settlements, a few appear repeatedly. Generic firm Barr Laboratories, for example, reached settlements with respect to eight different drugs.")

> *reasonable expectation* that the wrong will be repeated. The burden is a heavy one.

W. T. Grant, 345 U.S. at 632-33 (emphasis added, citations and footnotes omitted); *accord*, *Friends of Earth, Inc. v. Laidlaw Environmental Services (TOC), Inc.*, 528 U.S. 167, 189 (2000) ("It is well settled that a defendant's voluntary cessation of a challenged practice does not deprive a federal court of its power to determine the legality of the practice" unless it is "absolutely clear that the allegedly wrongful behavior could not reasonably be expected to recur.") (internal quotation marks and citations omitted).

The Court's rationale applies with even greater force where, as here, the challenged practice has been expressly deemed *lawful* by the lower courts. In these circumstances, the reasonable expectation is that repetition is not only possible, *but inevitable*. *See* Reply Brief 3-4, 1a (noting recent spike in reverse payment settlements). While courts cannot enjoin "all future violations of the antitrust laws," they can and should enjoin continuing unlawful practices, such as pay-for-delay settlements, that squelch generic competition. *Zenith*, 395 U.S. at 133 ("[W]hen the purpose to restrain trade appears from a clear violation of the law, it is not necessary that all of the untraveled roads to the end be left open and that only the worn one be closed.") (citation and quotation marks omitted).

In any event, the question presented relates to whether Petitioners alleged a violation of the Sherman Act in the first place, and not the scope of a potential injunction. The United States agrees that the lower courts were wrong in holding that Petitioners failed to allege such a violation. Petitioners do not contend that it is impossible for a challenge to such an agreement to reach this Court before the expiration of the pertinent patent, nor is such "evasion of review" necessary in order for a broad injunction to be available under *Zenith*. *Cf.* U.S. Br. 17. Instead, the limited life span of patents, the ubiquity of pay-for-delay agreements and their impact on the national economy, the conflicting circuit court standards, and the strong public interest

in antitrust enforcement, all militate strongly in favor of granting certiorari in this case.

2. In addition, the tamoxifen patent has been raised as a federal defense that immunizes conduct that would otherwise violate antitrust laws — federal or state. *See, e.g., Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1307 (11th Cir. 2003) ("The right of exclusion conferred by a patent has been characterized as a defense to an antitrust claim. . . ."); *In re Stock Exchanges Options Trading Antitrust Litig.*, 317 F.3d 134, 151 (2d Cir. 2005) ("Most immunities are affirmative defenses."). The same federal interests advanced by a grant of certiorari to address federal law claims are equally advanced by certiorari to address a federal law defense to a state law claim. Thus, even when a state court rejects a claim of federal preemption, such a decision is reviewable by the Court notwithstanding that the assertedly preempted claim is a state law claim *Franchise Tax Board*, 463 U.S. at 12 n. 12 (citing *Fidelity Federal Sav. & Loan Ass'n v. De la Cuesta*, 458 U.S. 141 (1982)).

3. Even absent the injunctive claim and the federal patent defense, the legality of reverse payment settlements is squarely raised by Petitioners' claims for damages under state antitrust statutes. The United States notes that "petitioners have not identified even a single state statute (of the many on which the complaint relied) that has been construed as being coterminous in all respects with federal antitrust law." *Id.* at 18. However, the United States conflates differences between state and federal law concerning who may bring suit (i.e., standing) with the *uniformity* of state and federal law concerning *conduct* that constitutes an antitrust violation. Differences between federal and state antitrust statutes generally relate only to jurisdiction (state violations need not impact interstate commerce) and injured parties who may assert claims for damages.[3] On the other

3. While indirect purchasers lack standing to bring suit for damages under Section 4 of the Clayton Act, 15 U.S.C. § 15, *see Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977), this Court has expressly left it to

(Cont'd)

hand, it is well recognized that *conduct* that violates Sections 1 and 2 of the Sherman Act also will violate corresponding state statutes.[4] In fact, many state antitrust statutes expressly adopt federal antitrust precedents as controlling guidance. *E.g.*, Ariz. Rev. Stat. § 44-1412; D.C. Code Ann. § 28-4515; Iowa Code § 553.2; N.M. Stat. Ann. § 57-1-15; S.D. Codified Laws § 37-1-22; W. Va. Code Ann. § 47-18-16.

It is not surprising, therefore, that the Court of Appeals' analysis focused exclusively on violation of the Sherman Act. The Court of Appeals rightly perceived that question to be dispositive, which belies the United States' far-fetched argument that "the relevance of that determination [of federal law] to the state laws at issue is entirely uncertain." U.S. Br. 18. As "the adequacy and independence of any possible state law ground is not clear from the face of the opinion," this Court should "accept as the most reasonable explanation" that the Court of Appeals "decided the case the way it did because it believed that federal law required it to do so." *Michigan v. Long*, 463 U.S. 1032, 1040-41 (1983). At a minimum, the Court of Appeals' "interpretation of state law has been influenced by an accompanying interpretation of federal law." *Three Affiliated Tribes*, 467 U.S. at 152. It is clearly appropriate for this Court to grant certiorari to correct such misapprehensions as to what conduct is unlawful under the Sherman Act.

(Cont'd)
the states to determine if state laws should permit indirect purchasers to bring antitrust damage suits. *See California v. ARC America Corp.*, 490 U.S. 93, 102-03 (1989).

4. *See, e.g., Grams v. Boss*, 294 N.W.2d 473, 480 (Wis. 1980) ("We have repeatedly stated that [Wis. Stat.] sec. 133.01, Stats., was intended as a reenactment of the first two sections of the federal Sherman Antitrust Act of 1890 ... and that the question of what acts constitute a combination or conspiracy in restraint of trade is controlled by federal court decisions under the Sherman Act."); *see also In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 900 (6th Cir. 2003); *U.S. v. Microsoft Corp.*, 87 F. Supp. 2d 30, 54 n. 7 (D.D.C. 2000), *affirmed in part rev'd in part on other grounds by*, 253 F.2d 34 (D.C. Cir. 2001).

B. The United States may be correct that the precise factual circumstances of this case are unlikely to recur, but any unique facts do not detract from the question squarely raised in the petition — *i.e.*, under what general circumstances are reverse payment settlements to exclude generic competition unlawful? There is certainly no suggestion that application of the erroneous standard adopted by the Court of Appeals is limited by the unique facts of this case. *Cf.* U.S. Br. 16 n. 7 (suggesting that *Cardizem* does not extend beyond the purportedly unique circumstances there); *see also* Jon Leibowitz, *Exclusion Payments to Settle Pharmaceutical Patent Cases: They're B-a-a-ack!* (April 24, 2006) at 7-8.[5] The Court of Appeals recognized that, notwithstanding unique facts, "the issues presented have been much litigated and appear to retain their vitality." Pet. App. 2a. The primary "uniqueness" that the United States identifies in this case involves a change in the law governing vacatur of judgments. U.S. Br. 19. As the United States recognizes, however, that fact is germane only to a more general assessment of the strength of the patent. *Id.* Such an assessment of patent strength could involve anything in the entire realm of patent law, and thus will involve "unique facts" in every case. To wait for some hypothetical, unidentified future case having no "unique facts" would simply leave important legal issues unresolved indefinitely.

Indeed, by contending that because the challenged agreements occurred after a judgment of patent invalidity, a decision emphasizing that factor "might shed little light on the proper disposition of future cases challenging reverse-payment settlements in other factual settings," U.S. Br. 19, the United States seems to suggest that certiorari should be denied because Petitioners' case — which they *lost* below — is *too strong* on the merits to produce a generally applicable precedent. This Court is able to craft its opinions to avoid undue emphasis on one case's particular facts. Speculation to the contrary should

5. *Available at:* http://www.ftc.gov/speeches/leibowitz/060424PharmaSpeechACI.pdf.

not trump the strong public interest in ensuring proper antitrust enforcement, especially in an unusually *strong* case. *See Zenith Radio*, 395 U.S. at 130-31.

C. Finally, the United States suggests that it may be preferable to await a case that arises under the post-2003 regulatory regime, further noting that Congress is considering legislation that would prohibit reverse payments in settlements with ANDA filers. U.S. Br. 19-20 & n.9 (citing S. 316, 110th Cong., 1st Sess. § 3 (2007); H.R. 1902, 110th Cong., 1st Sess. § 2 (2007)).[6] This suggestion is very odd, given that in its brief in the *Schering* case, the other cases identified as a basis for assuming that a conflict could "develop" were all pre-2003 cases. Brief for the United States as Amicus Curiae in *FTC v. Schering-Plough Corp.*, No. 05-273 (dated May 2006) at 19 ("Schering Br.").

The United States' brief unreasonably exaggerates the significance of the 2003 amendments. The Second Circuit separately rejected the aspect of Petitioners' allegations that rested on alleged conspiracy with Barr to manipulate the 180-day exclusivity period, on four separate legal grounds. Pet. App. 59a-64a. Petitioners have not included any of those four legal issues in their question presented. Instead, the only legal issue that Petitioners have sought to raise with this Court is a broad question, concerning lawfulness of settlement agreements

6. Even if the legislative process ultimately prohibits reverse payment settlements with ANDA filers, U.S. Br. 20 n.9 — at best, a highly uncertain proposition — there will be no remedy for the breast cancer patients and prescription benefit providers who were harmed by paying supra-competitive prices for tamoxifen. The proposed legislation applies only to pharmaceuticals, and the Court of Appeals' opinion may inspire similar anticompetitive agreements in other industries. Moreover, even in the pharmaceutical context, the proposed legislation has been criticized by defense attorneys as an "indiscriminate legislative solution to a delicate problem." N. Stoll and S. Goldfein, *Reverse Payments: A Question for Court or Congress*?, New York Law Journal (April 17, 2007). "Individual examination of reverse payment agreements by courts, under a proper standard articulated by the Supreme Court, is the best way to make sure procompetitive brand-generic settlements are promoted and anticompetitive horizontal allocations are prevented." *Id.*

themselves, as to which pre-2003 and post-2003 cases do not differ. This case presents a straightforward opportunity to address that important question now. *See* Pet. 9-10.

It is highly unlikely that post-2003 agreements — if they are subjected to antitrust enforcement at all — will present the issues with greater clarity. As recently explained in testimony before Congress, reverse payment settlements have occurred in two distinct waves.[7] The first wave began in 1993 and ended in 2000, after the Federal Trade Commission made clear its opposition to pay-for-delay settlements. The second wave began in 2005, in "direct response to the failure of federal courts [in *Schering-Plough* and *Tamoxifen*] to recognize and resolve the pay-for-delay issue." Hemphill Testimony at 8. "That failure is likely to be compounded, moreover, by an evolution in the means by which innovators now pay for delay." *Id.*

> In the earliest settlements, such as tamoxifen, BuSpar, Zantac and Cipro settlements, payment *was a relatively straightforward affair*. In exchange for the generic firm's delayed entry, the brand-name firm paid cash. Modern settlements also entail payment for delay, *but the parties avoid a straight conveyance of cash*, preferring instead to employ a variety of alternative forms of payment.

Id. at 8-9 (emphasis added). In sum, in light of uncertainties created by divergent legal standards in the different Circuits, brand-name firms increasingly rely upon complicating side deals as "means to smuggle compensation to the generic firm." *Id.* at 9. Such side deals in the post-2003 regulatory environment are likely to present significantly *more* "unique facts" than this case does. *Cf.*, Schering Br. at 12-13 (recommending denial of certiorari because, *inter alia*,

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7. Testimony of C. Scott Hemphill, Associate Professor, Columbia Law School, House Committee on Energy and Commerce, Subcommittee on Commerce, Trade and Consumer Protection, Hearing on H.R. 1902, Protecting Consumer Access to Generic Drugs Act of 2007 (May 2, 2007) ("Hemphill Testimony") at 7; *available at:* http://energycommerce.house.gov/cmte_mtgs/110-ctcp-hrg.050207.Hemphill-testimony.pdf.

"[t]he court of appeals determined that Schering's $60 million payment to Upsher was not compensation for delayed market entry by Upsher, but was instead an independent and bona fide royalty payment by Schering to license Upsher's product.") (citation to record omitted).

Opportunities for this Court to address comparatively straightforward, "first wave" agreements are dwindling.[8] To await some other, unidentified "vehicle" that hypothetically might be more "attractive" for review is a recipe for the indefinite postponement of important issues, which the United States concedes already have generated a split between the Circuits, and which create serious legal planning uncertainties for pharmaceutical companies on a regular basis. Moreover, while this Court awaits a hypothetically "more attractive" vehicle, drug purchasers, including the United States and Petitioners, would continue to pay countless billions in overpayments, as the "second wave" of pay-for-delay deals triggered by the erroneous decision of the Second Circuit below continues unabated. In view of the United States' recognition that the decision below applied an incorrect legal standard, that the legal standard applied is too lax, and that the legal question raised is important and should be settled by this Court, certiorari should be granted. *See* Pet. App. 125a (Pooler, J., dissenting) ("A more searching inquiry and a less stringent standard are required to properly protect all interests.").

CONCLUSION

For the foregoing reasons and those stated in our petition and reply, the petition for a writ of certiorari should be granted.

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8. We are not aware of any pending antitrust litigation concerning Zantac or Buspar. Antitrust litigation concerning Cipro, which resulted in summary judgment in favor of defendants (*Ciprofloxacin*, 363 F. Supp. 2d 514), is currently on appeal in the same court that produced the divided opinion below. *See* 2d Cir. nos. 05-2851, 05-2852 & 05-2863. Merits briefing for *Ciprofloxacin* has been suspended pending resolution of a motion to transfer the cases to the federal circuit. Here, the Court of Appeals relied heavily on the *Ciprofloxacin* decision in upholding dismissal. *See* Pet. 11.

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June 2007

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No. 06-830

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IN THE

Supreme Court of the United States

In Re: TAMOXIFEN CITRATE ANTITRUST LITIGATION

JOBLOVE, ALLIED SERVS., DIV WELFARE FUND, BENNISH, KOONAN, GREAT LAKES HEALTH PLAN INC., LACAVA, DONEGA, SMITH, LOVINGER, WOOLLACOTT, WHITESIDE, PLATT, UNDERWOOD, TEAMSTERS LOCAL 237, LYNCH, CALLAWAY, MALONEY, MECHANICAL CONTRACT, IBEW-NECA LOCAL 505 HEALTH & WELFARE PLAN, A.F. OF L. – A.G.C. BUILDING TRADES WELFARE FUND, SHEET METAL WORKERS LOCAL 441 HEALTH & WELFARE PLAN, LOCAL 1199 NAT'L BENEFIT FUND FOR HEALTH AND HUMAN SERVICES, NEW YORK STATEWIDE SENIOR ACTION COUNCIL, MARKS, BLONSTEIN,

Petitioners,

v.

BARR LABS., INC., ASTRAZENCA PHARMACEUTICALS LP, ZENECA INC., ASTRAZENECA PLC,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

REPLY BRIEF

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STATEMENT PURSUANT TO RULE 29.6

Petitioners' corporate disclosure statement was set forth at page *ii* of the Petition for a Writ of Certiorari, and there are no amendments to that statement.

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1. This case puts into sharp focus an issue that is fundamental to antitrust doctrine in the Hatch-Waxman context: whether a branded drug seller can buy protection from potential generic competition so long as the competition excluded falls within the nominal scope of a non-sham patent claim. Petitioners (plaintiffs below) show that certiorari is warranted to reconcile the inconsistent standards applied by courts of appeals. Pet. 12-15; *accord* Brief of *Amicus Curiae* National Association of Chain Drug Stores in Support of Petitioners ("NACDS Br.") 3-9; Brief of *Amicus Curiae* the American Antitrust Institute in Support of Petitioners ("AAI Br.") 14-16;[1] Brief Amici Curiae of 41 Professors of Economics, Business and Law in Support of Granting the Petition ("41 Profs. Br.") 1-3. In their opposition, Respondents (defendants below) attempt to isolate unique facts of each court of appeals case to conjure up some baseline, hypothetical consistency. Resp. Br. 9-13.

Even if the ultimate outcomes of these cases could somehow be reconciled on the basis of individual facts — and they cannot[2] — the *standards* employed by the Second, Sixth and Eleventh Circuits are purposely inconsistent. In *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003), the Eleventh Circuit *expressly* disagreed with the Sixth Circuit. 344 F.3d at 311 n.26 ("To the extent that the Sixth Circuit [in *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003)] suggests that a settlement of patent litigation was a per se violation of the antitrust laws merely because it involves a generic's agreement to delay marketing until resolution of the patent infringement case in exchange for exit payments, *we respectfully disagree*. We believe that the potential exclusionary power of the patent must first be considered.")

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1. The AAI Brief also describes a division between the three branches of government. *See* AAI Br. 10-13.

2. *See, e.g.*, 1 Herbert Hovenkamp, Mark D. Janis, and Mark A. Lemley, *IP and Antitrust, An Analysis of Antitrust Principles Applied to Intellectual Property Law* § 7.4, at p. 7-41 (2007 Supp.) ("Courts and agency decisions evaluating exclusion payments have led to widely different outcomes."); *see also id.* at 7-41 - 7-51 (addressing *Cardizem*, *Schering*, *Valley Drug*, *Tamoxifen*).

(emphasis added); *accord Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1065 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006).[3] In this case the Second Circuit went even further, deeming exclusion payments (regardless of amount) immune from antitrust liability so long as (1) the patent, even if "fatally weak," is not a sham, and (2) the exclusion does not exceed the patent's facial scope. Pet. App. 48a-49a; *see also* 1 *IP and Antitrust*, § 7.4, at p. 7-48 ("The Second Circuit has shown even more lenient treatment toward exclusion payments than the Eleventh Circuit."). This Court should grant certiorari to eliminate the stark divergences that exist between the legal standards adopted by the circuit courts.

2.a. The 2003 Medicare Amendments require the submission of Hatch-Waxman settlement agreements to the FTC (Pet. App. 154a-156a), reflecting congressional concern over the anticompetitive effects of these agreements. Respondents, ignoring the purpose of this legislation, find it notable that "after the dismissal of petitioners' claims by the district court in this case," Congress required parties who settled infringement actions to file copies of their settlements with the FTC, "but took no action to limit the terms of settlement." Resp. Br. 22-23 (footnote omitted).

Respondents' claim to congressional blessing of the result in the case is specious. It is more significant that Congress passed the 2003 Medicare Amendments *after* the circuit court rulings in *Cardizem* and *Andrx Pharms., Inc. v. Biovail Corp.*, 256 F.3d 799, 801 (D.C. Cir. 2001). These prominent rulings reflected the prevailing interpretation of antitrust law at the time Congress acted. *See also* AAI Br. 11-12 (noting that a representative of the brand manufacturers' trade association testified in Congress that a reporting requirement was all that was needed because exclusion payments violate the Sherman Act). Thus, the *antitrust*

3. *See also In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp.2d 1279, 1315 n.36 (S.D. Fla. 2005) ("The Eleventh Circuit [in *Valley Drug*] disagreed with the Sixth Circuit's approach in *Cardizem*, because that Court did not conduct an analysis of the exclusionary potential of the patent and also placed considerable reliance on the size of the exit payments.").

laws "limit the terms of settlement" between horizontal competitors and, by requiring that pharmaceutical companies submit their settlement agreements to the FTC, Congress sought to further the FTC's ability to enforce those laws. *See* S. Rep. No. 167, 107 Cong., 2d Sess., 2002 WL 1350511 (June 20, 2002) at 4 (Congress sought to stamp out the "abuse of the Hatch-Waxman law" resulting from "pacts between big pharmaceutical firms and makers of generic versions of brand name drugs, that are intended to keep lower-cost drugs off the market."). If the decision below stands, however, the FTC will be left with precious little to enforce, at least in the Second Circuit. *See* 1 *IP and Antitrust*, § 7.4, at p. 7-49 ("The result is that in the Second Circuit, exclusion payments are legal per se unless the lawsuit is not only weak but a sham, a standard that is virtually impossible to surmount.") (footnote omitted).

Based upon the agreements submitted to the FTC, Commissioner Jon Leibowitz commented on April 26, 2006 about the apparent increase in the number of exclusion payments. Pet. 16-17; *see also* NACDS Br. 9-13; 41 Profs. Br. 10-11. On January 17, 2007, the FTC released its final report on agreements filed with the FTC during fiscal year 2006.[4]

> In FY 2006, fourteen of the twenty-eight final settlements that the Commission received (50%) included provisions in which the generic manufacturer received some form of compensation from the manufacturer of the brand product at issue in the litigation and restrictions on the generic manufacturer's ability to enter with its product. By comparison, in FY 2005 only 3 of the 11 final settlements (27%) included both the compensation to the generic and a restriction on the generic's ability to enter, and, in FY 2004, no agreements involved both compensation and restriction.

4. Federal Trade Commission, *Agreements Filed With the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in Fiscal Year 2006: A Report by the Bureau of Competition* (filed Jan. 17, 2007), *available at*: http://www.ftc.gov/opa/2007/01/drugsettlements.htm.

> The fourteen agreements received in FY 2006 settled patent litigation on eight different branded pharmaceutical products. *Each of the agreements involved a product with 2005 U.S. annual sales exceeding $125 million; eight of the agreements involved products with 2005 U.S. annual sales of more than $450 million.*

Id. at 4 (emphasis added); *see also id.* Figure III (Reply App. 1a).

The Eleventh Circuit's decision in *Schering* and the Second Circuit's initial decision in this case, 429 F.3d 270, are largely (if not exclusively) responsible for the disturbing increase in anticompetitive settlements. *See* Jon Leibowitz, *Exclusion Payments to Settle Pharmaceutical Patent Cases: They're B-a-a-ack!* (April 24, 2006) at 7-8[5] ("If the *Schering* and *Tamoxifen* decisions are not reversed — that is, if branded firms are empowered by the courts to pay the generic more than it would have made by competing — these rivals will have *carte blanche* to avoid competition and share resulting profits, and we will see minimal competition before patent expiration."); C. Scott Hemphill, *Drug Patent Settlements, 1993-2006*, Columbia Law School Working Paper (2007), at 2[6] (*Schering* and *Tamoxifen* rulings "have led to a flood of new settlements . . . [in which] the generic firm agrees to abandon its patent challenge and delay entry in exchange for payment from the innovator.")

b. Respondents also find comfort in the FTC's discussion in its *Schering* opinion of the district court's opinion below. Resp. Br. 25-26 (quoting *In re Schering-Plough Corp.*, FTC Docket No. 9297, 2003 FTC LEXIS 187, at *71 (FTC Dec. 8, 2003), *rev'd, Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005)). According to Respondents, the FTC "did not retract its endorsement of the result in this case." *Id.* at 26. The FTC's comment was not an "endorsement" of the result in the

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5. *Available at* http://www.ftc.gov/speeches/leibowitz/060424PharmaSpeechACI.pdf.

6. *Available at* http://www2.law.columbia.edu/contracteconomics/papers/papers.html.

district court, but merely an effort to distinguish that decision from the facts before it. The comment derives from the district court's misconstruction of Petitioners' complaint, as it does not even mention that the tamoxifen patent had been held invalid and unenforceable *at the time of the agreements.* The *status quo* at the time of agreement was an important aspect of the FTC's rationale. Moreover, the FTC's amicus brief in support of rehearing in this case states that "the panel majority opinion conflicts with basic principles of antitrust law in numerous respects, the most egregious example of which is condoning agreements that harm competition and consumers on the ground that they make 'economic sense' to the parties who profit from them." Brief of Amicus Curiae Federal Trade Commission (Nov. 30, 2005) at 2.[7] The FTC has not retracted its endorsement of this view.

3. Petitioners show that the Second Circuit decision misapplied settled antitrust law in a number of crucial respects. Pet. 17-27; *see also* NACDS Br. 13-20; AAI Br. at 16-20; 41 Profs. Br. 4-10. In opposition, Respondents reiterate, as the Second Circuit held, that so long as they did not restrain generic entry beyond the facial scope of the '516 patent, they were free to resolve the patent infringement litigation on virtually any terms that they wished. Resp. Br. 13-26. While exceeding the scope of the patent would obviously raise antitrust concerns, it is not the only inquiry. *See* NACDS Br. 16-17.[8] Even holders of valid patents are liable for antitrust violations when they combine with horizontal competitors to exclude competition. *See, e.g.,*

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7. *Available at:* http://www.ftc.gov/os/2005/12/051202 amicus tamoxifen.pdf.

8. *See Blonder-Tongue Labs. Inc. v. University of Illinois Found.*, 402 U.S. 313, 343 (1971) ("The far-reaching social and economic consequences of a patent, therefore, give the public a paramount interest in seeking that patent monopolies spring from backgrounds free from fraud or other inequitable conduct and that such monopolies are kept within their legitimate scope") (quoting *Precision Instrument Mfg. Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806, 816 (1945)).

Andrx, 256 F.3d at 813 n.15 ("[E]ven a patent-right holder is not immune from antitrust liability."); *United States v. Microsoft Corp.*, 253 F.3d 34, 63 (D.C. Cir. 2001) (*en banc*) ("Intellectual property rights do not confer a privilege to violate the antitrust laws.") (citation omitted).

a. Respondents contend that it is immaterial whether Barr received consideration in excess of the profits it could have made by marketing its own generic product, Resp. Br. 21-22, but this shows that Respondents negotiated an allocation of the expected consumer surplus, rather than a compromise of the patent infringement litigation.[9] *See* AAI Br. at 6-7. There was no "compromise" or "settlement" of the infringement litigation — a successful challenge to the patent was *eliminated* by exclusion payments to the alleged infringer.[10] If litigants in

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9. *See* FTC Commissioner Thomas B. Leary, *Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes, Part II* (May 17, 2001) at p 5 ("The inference that the parties really intend to share monopoly profits for the period of deferred entry — however long it may be — would be particularly strong if the payments exceed the projected profits of the generic firm for that period.") (footnote omitted), *available at:* http://www.ftc.gov/speeches/leary/learypharmaceutical settlement.htm.

10. Barr (and its supplier) received $56.9 million in cash and Barr secured a lucrative distribution arrangement, through which it enjoyed nine years of tamoxifen sales at "branded" prices without generic competition. For the fiscal year ended June 30, 2001, for example, Barr reported tamoxifen sales of more that $332 million. Barr Form 10-K405, filed August 24, 2001 at 3 ("Tamoxifen accounted for approximately 65%, 68% and 66% of our product sales during fiscal 2001, 2000, and 1999, respectively."), *available at*: http://phx.corporate-ir.net/phoenix.zhtml?c=60908&p=irol-sec&secCat01.1_rs=431 &secCat01.1_rc=10. Barr maintained these sales in a market that Barr helped shelter from generic competition. With the emergence of true generic competition in 2003, Barr's tamoxifen sales plummeted. *See* Barr's November 6, 2003 financial press release ("As expected, sales of Tamoxifen, an anti-cancer agent that the Company distributed until November 2002 and launched as a manufactured product in February 2003, declined to *$3.1 million* in first quarter of fiscal 2004 from *$76.0 million* in the first quarter of fiscal 2003.") (emphasis added), *available at*: http://phx.corporate-ir.net/phoenix.zhtml?c=60908&p=irol-newsArticle&ID=467263&highlight=.

Hatch-Waxman patent infringement litigation are immunized from antitrust liability by a general policy favoring "settlement," as the Second Circuit held (Pet. App. 48a-49a), it must be expected that generic manufacturers will "settle" on terms that they deem most profitable. No rational generic company could refuse a "settlement offer" of more money than it could earn by invalidating the patent and marketing a competing product. "Instead of racing to file ANDAs to compete, [generic manufacturers] will be racing to file ANDAs to be first to settle — the first to be paid not to compete."[11] Such a prospect is antithetical to the antitrust laws. *See United States v. Citizens & S. Nat'l Bank*, 422 U.S. 86, 116 (1975) ("The central message of the Sherman Act is that a business entity must find new customers and higher profits through internal expansion — that is, by competing successfully rather than by arranging treaties with its competitors.").

b. In addition, Respondents argue that crediting allegations concerning the initial ruling of patent invalidity[12] would "wrongly ascribe preclusive significance to a vacated judgment" and that "any inference that might be drawn from the initial patent ruling is undermined by AstraZeneca's later successes defending the '516 patent." Resp. Br. 18 (citing Pet. App. 34a & n.17). The district court, in fact, afforded dispositive weight to subsequent patent challenges, initiated by relatively unmotivated generic challengers,[13] that failed to prove the '516

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11. Jon Leibowitz, *How Settlements Make Strange Bedfellows: Or How the Federal Trade Commission has Managed to Unite the Entire Pharmaceutical Industry (but only in Opposition to the FTC's Position on Exclusion Payment Settlements* (Sept. 29, 2006) at 10, *available at*: http://www.ftc.gov/speeches/leibowitz/060929GPHApubvers.pdf.

12. *Imperial Chem. Indus., PLC v. Barr Labs., Inc.*, 795 F. Supp. 619 (S.D.N.Y. 1992), *vacated pursuant to settlement sub nom. Imperial Chem. Indus., PLC v. Heumann Pharma GmbH & Co.*, 991 F.2d 811 (Fed. Cir. 1993) (table).

13. *See* Pet. 24-27 (citing C. Scott Hemphill, *Paying for Delay*, 81 N.Y.U. L. Rev. 1553, 1586 (Nov. 2006) ("Generic firms other than the

(Cont'd)

patent invalid or unenforceable. The Second Circuit held that it "was appropriate for the district court to take these decisions into account for the limited purpose of rebutting the plaintiffs' conclusory allegation that the Federal Circuit would have affirmed Judge Broderick's decision invalidating the tamoxifen patent." Pet. App. 34a n.17 (citations omitted). The apparent crux of the courts' reliance on the subsequent determinations is that the judgment in *ICI v. Barr* must have been "wrong," and, therefore, Respondents' private agreements could not harm Petitioners.

This approach is erroneous, especially on a motion to dismiss, because (1) the agreements must be evaluated on the basis of the facts that existed at the time they were entered (*see, e.g., Valley Drug*, 344 F.3d at 1306 ("We begin with the proposition that the reasonableness of agreements under the antitrust laws are to be judged at the time the agreements are entered into.")), which in this case was at a time when the patent had been held to be invalid and unenforceable, and (2) it ignores the standard of appellate review that would have applied in *ICI v. Barr*. A trial judge's findings of fact are reviewed for clear error only. Fed. R. Civ. P. 52(a). *See Shelcore, Inc. v. Durham Indust., Inc.*, 745 F.2d 621, 624-25 (Fed. Cir. 1984) ("The presumption of validity does not guide our analysis on appeal."). "If the district court's account of the evidence is plausible in light of the record viewed in its entirety, the court of appeals may not reverse it even though convinced that had it been sitting as the trier of fact, it would have weighed the evidence differently." *Anderson v. City of Bessemer*, 470 U.S. 564, 573-74 (1985). Moreover, "special deference" is paid to findings of fact where the trial court bases its determinations on assessments of witnesses' credibility. *Id.* at 574. This is particularly true where, as here, the trial court's findings of

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(Cont'd)

first filer will be behind in the approval process, if they have bothered to file at all; they will also be less motivated to initiate or vigorously pursue the challenge.")).

fraudulent conduct were expressly based on clear and convincing evidence. *See ICI v. Barr*, 795 F. Supp. at 621.

Thus, other generic manufacturers' failure, at least four years later, to demonstrate that the '516 patent is invalid has no bearing on the status quo at the time of the agreements or the appellate prospects of *ICI v Barr*. In *Zeneca Ltd. v. Novopharm Ltd.*, 111 F.3d 144, 1997 WL 168318 (Fed. Cir. 1997) (table), for example, the subsequent ANDA-IV filer (Novopharm Ltd.) appealed the finding that Zeneca had not acted with deceptive intent in connection with the '516 patent:

> We do not agree that the district court committed clear error in failing to find that deceptive intent on the part of Zeneca has been proven by clear and convincing evidence. At best, the evidence cited by Novopharm *reveals the existence of two permissible views of the evidence*. Based on the entire record, we are not left with the definite and firm conviction that the district court committed a mistake; its findings are clearly plausible. *They cannot be clearly erroneous just because contrary findings would also be plausible*. . . .

1997 WL 168318, at *3 (emphasis added). In contrast, the factual findings in *ICI v. Barr* adhered to Barr's view of the evidence — that clear and convincing proofs demonstrated that Zeneca *had* acted with deceptive intent. Zeneca avoided this judgment not on the strength of the '516 patent, but by combining with its competitor Barr to preserve its tamoxifen monopoly and share the monopoly rents. It was erroneous for the lower courts to rely upon subsequent decisions as a basis to brand Petitioners' well-pleaded allegations as "conclusory."[14] As Judge Pooler's dissent correctly recognized, those subsequent victories could not have existed but for the deal with Barr. *See* Pet. App. 131a

14. Moreover, Petitioners here are strangers to the infringement actions against generic manufacturers and the requirements of due process preclude giving "conclusive effect to a prior judgment against one who is neither a party nor in privity with a party therein." *Richards v. Jefferson County*, 517 U.S. 793, 797, n.4 (1996) (citation omitted).

("[T]here is a certain unfairness in using the subsequent litigation, which would not have existed had Barr prevailed on appeal, to demonstrate that plaintiffs cannot establish that Barr would have prevailed on appeal.").[15]

4. Petitioners further show that this case presents an ideal opportunity for the Court to address the practice of pharmaceutical exclusion payments, in part because it arises from a dismissal motion that is uncomplicated by factual findings such as those that the Solicitor General found troubling in *Schering*. Pet. 9-11. Respondents counter that this case is a "poor vehicle" to address these issues because of intervening changes in the law, including the 2003 Medicare Amendments. Resp. Br. 26-28.[16] Although some of the peripheral factual circumstances may have been addressed by subsequent court decisions or legislation, no one has suggested that the central issue of the litigation — exclusion payments to manufacturers of generic pharmaceuticals — is unlikely to recur. Indeed, it *is* recurring at an alarming rate. *See* FTC FY 2006 Report, Jan. 17, 2007 (fn. 4, *supra*). Respondents' contention also ignores the Second Circuit's observation "the issues presented have been much litigated and appear to retain their vitality." Pet. App. 2a.

CONCLUSION

For the foregoing reasons and those stated in our petition, the petition for a writ of certiorari should be granted.

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15. With different presentations and different fact-finders, it is not unprecedented for one challenger to fail and another succeed. *See, e.g., Dana Corp. v. NOK, Inc.*, 882 F.2d 505 (Fed. Cir. 1989); *Mississippi Chem. Corp. v. Swift Arg. Chem. Corp.*, 717 F.2d 1374 (Fed. Cir. 1983). Once a challenger succeeds in defeating the patent, however, all other potential entrants will benefit from collateral estoppel. *See Blonder-Tongue Labs., Inc. v. University of Illinois Found.*, 402 U.S. 313 (1971); *Pharmacia & Upjohn Co. v. Mylan Pharm., Inc.*, 170 F.3d 1373, 1379 (Fed. Cir. 1999).

16. There is no dispute – not even from Respondents (Resp. Br. 28) – that state antitrust claims are interpreted in accordance with federal antitrust law pursuant to either an express harmonization provision or judicial decision. *See Cardizem*, 332 F.3d at 906 ("It is undisputed that the state antitrust statutes at issue either follow federal Sherman Act precedent or find federal case law persuasive.").

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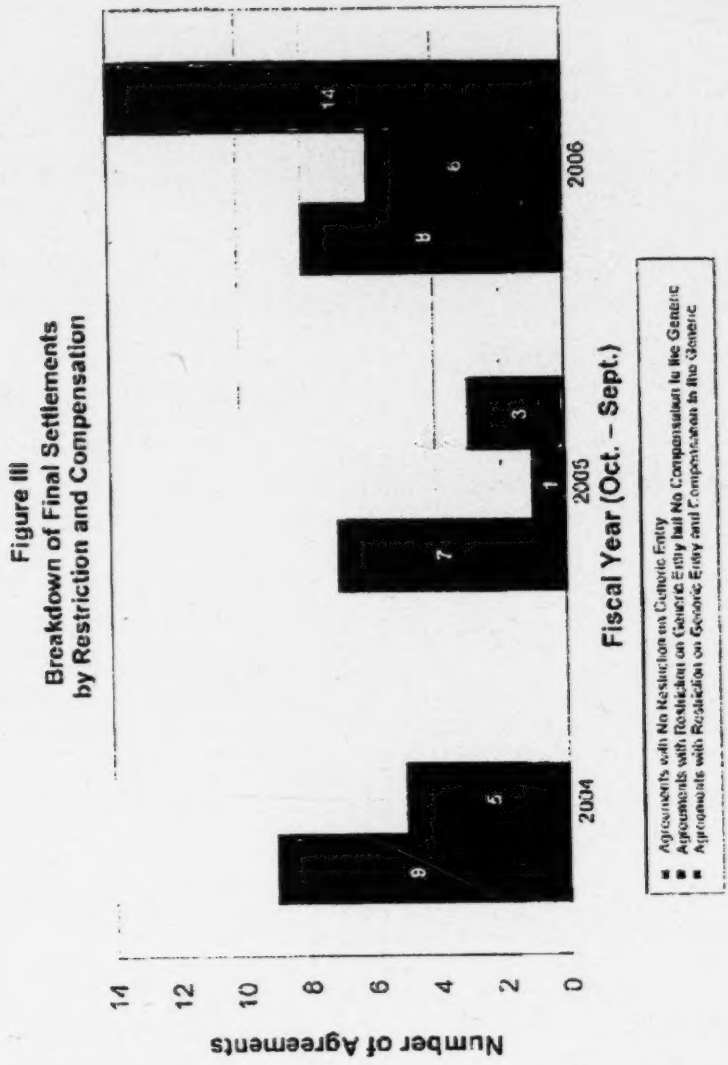
APPENDIX

APPENDIX



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No. 06-830

In the Supreme Court of the United States

BETTY JOBLOVE, ET AL., PETITIONERS

v.

BARR LABORATORIES, INC., ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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QUESTION PRESENTED

Whether the federal antitrust laws prohibit a brand name drug patent holder and a prospective generic competitor from settling patent infringement litigation by agreeing that the generic manufacturer will not challenge the validity of the patent or market its own version of the drug until the expiration of the patent, in exchange for a substantial payment from the patent holder.

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ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

This brief is submitted in response to the Court's order inviting the Solicitor General to express the views of the United States. The United States submits that the petition for a writ of certiorari should be denied. Although the petition presents an important and difficult question, and the court of appeals adopted an incorrect standard, this case does not appear to be a good vehicle for resolving the question presented.

STATEMENT

Respondent AstraZeneca PLC (Zeneca),[1] a pharmaceutical company, marketed tamoxifen citrate (tamoxifen), the most widely prescribed drug for the treatment of breast can-

[1] Respondents AstraZeneca Pharmaceuticals LP and Zeneca Inc. are subsidiaries of AstraZeneca PLC (or its corporate predecessor); Imperial Chemical Industries PLC (ICI) was the parent of AstraZeneca PLC's predecessor. This brief refers to respondents (and, where appropriate, ICI) collectively as Zeneca.

cer, under the brand name Nolvadex. Zeneca held a patent for the drug, United States Patent No. 4,536,516 (the '516 patent). In 1987, Zeneca sued respondent Barr Laboratories after Barr proposed to market a generic version of tamoxifen that would allegedly infringe Zeneca's patent. After the district court held Zeneca's patent invalid, Zeneca and Barr entered into a settlement providing, *inter alia*, that Zeneca would make a cash payment to Barr and that Barr would not market its generic version of the drug until after the patent expired. Petitioners, purchasers of tamoxifen and others, then filed suit against respondents under the federal antitrust laws and the laws of various States, contending that the settlement agreement unlawfully restrained competition. The district court dismissed the complaint, Pet. App. 70a-107a, and the court of appeals affirmed, *id.* at 1a-69a, 110a-135a.

1. The settlement at issue here arose against the statutory backdrop of the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act or the Act), Pub. L. No. 98-417, 98 Stat. 1585. The Hatch-Waxman Act establishes procedures designed to facilitate the market entry of lower-priced generic drugs while maintaining incentives to invest in new drug development. Under the Act, a company seeking approval from the Food and Drug Administration (FDA) to market a new drug must file a New Drug Application (NDA) demonstrating the safety and efficacy of its product. 21 U.S.C. 355(b). Once an NDA has been approved and a company starts marketing a "brand name" version of the drug, a company seeking to market a generic version of that drug may file an Abbreviated New Drug Application (ANDA) demonstrating that its product is the "bioequivalent" of its brand name counterpart. 21 U.S.C. 355(j).

If the brand name version of the drug is the subject of one or more patents, FDA may not make its approval of an ANDA effective before the expiration of any such patent, unless the applicant makes a "paragraph IV certification" that such patent is either invalid or not infringed by the generic version.

21 U.S.C. 355(j)(2)(A)(vii)(IV). If the patent holder files an action for infringement within 45 days of receiving notification of that certification, FDA's approval is automatically stayed for 30 months (unless the patent expires or a court holds the patent invalid or not infringed). *Ibid.* Under the version of the Hatch-Waxman Act in effect at the time of the relevant events, the first company to file an ANDA with a paragraph IV certification for a particular drug was granted the exclusive right to market the generic version until 180 days after the earlier of two dates: (1) when the company began commercial marketing of the generic version, or (2) when a court held the patent invalid or not infringed. 21 U.S.C. 355(j)(5)(B)(iv) (1984).[2]

2. Barr filed an ANDA to market a generic version of tamoxifen. In 1987, Barr amended its ANDA to include a paragraph IV certification; shortly thereafter, Zeneca sued Barr for patent infringement in the United States District Court for the Southern District of New York. In 1992, the district court held the '516 patent invalid and unenforceable on the ground that, in a predecessor patent application, Zeneca had fraudulently withheld data regarding the hormonal effects of tamoxifen on mice. *Imperial Chem. Indus., PLC* v. *Barr Labs.*, 795 F. Supp. 619, 621-622 (S.D.N.Y. 1992).

Zeneca appealed to the Federal Circuit. While that appeal was pending, Zeneca and Barr entered into a settlement, conditioned on vacatur of the judgment invalidating the '516 patent. The settlement provided that Barr would receive a cash payment of $21 million from Zeneca, withdraw its paragraph IV certification and its challenge to the validity of the patent, and enter into a license with Zeneca for the duration of the patent term, under which Barr would be allowed to market tamoxifen supplied by Zeneca. According to petitioners,

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[2] In 2003, Congress provided for forfeiture of the exclusivity period in various circumstances, and also provided that any generic manufacturer that filed an ANDA with a paragraph IV certification on the same day as the first filer would be treated as a first filer itself. See pp. 19-20, *infra*.

Zeneca and Barr also agreed that Barr would not market its generic version of the drug until the patent expired. If another generic manufacturer successfully invalidated the patent, the parties allegedly understood that Barr would attempt to invoke the exclusivity period on the basis of its previous paragraph IV certification (and argue that the exclusivity period would not begin to run until Barr began commercial marketing of the generic version of the drug); if it were successful, Barr would effectively discourage any other generic manufacturer from entering the market until the patent expired.[3] Pet. App. 74a-75a; C.A. App. A50-A51.

As agreed, Zeneca dismissed its appeal, and Zeneca and Barr moved to vacate the district court's decision. Consistent with its practice at the time, the Federal Circuit granted the parties' motion. *Imperial Chem. Indus., PLC* v. *Heumann Pharm. GmbH & Co.*, 991 F.2d 811 (1993) (Table).

Three other companies later filed ANDAs with paragraph IV certifications for generic versions of tamoxifen. Zeneca sued all three for patent infringement and prevailed. While that patent infringement litigation was still pending, Barr attempted to invoke the 180-day exclusivity period, but FDA (after litigation on the issue) ultimately refused to allow it to do so. Pet. App. 76a-78a.

3. On February 13, 2002, various plaintiffs (including petitioners) filed a class action against Zeneca and Barr in the United States District Court for the Eastern District of New York. C.A. App. A19-A79. In their complaint, plaintiffs alleged that the settlement unlawfully restrained competition

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[3] Zeneca and Barr entered into the settlement in 1993. In 1994, FDA published a rule providing that a company could avail itself of the exclusivity period only if it "successfully defended" against a suit for patent infringement; in 1998, FDA announced that it would no longer enforce that rule. See Center for Drug Evaluation & Research, FDA, *Guidance for Industry: 180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act* 3-4 (1998) <http://www.fda.gov/cder/guidance/2576fnl.pdf>.

by preventing Barr (and others) from marketing generic versions of the drug, thereby enabling Zeneca to continue monopolizing the market for tamoxifen. *Id.* at A36-A60. The complaint sought injunctive and declaratory relief under Sections 1 and 2 of the Sherman Act, 15 U.S.C. 1 and 2, see C.A. App. A64-A67, and also sought injunctive and declaratory relief and damages under the "antitrust and/or consumer protection laws" of 21 States (and the District of Columbia) that allegedly allowed the recovery of damages by indirect purchasers, see *id.* at A69-A75.

Respondents moved to dismiss the complaint for failure to state a claim. On August 20, 2002, Zeneca's patent expired. At oral argument on respondents' motion to dismiss, respondents asserted that the expiration of the patent mooted plaintiffs' Sherman Act claims. 9/27/02 Tr. 15-16. Respondents, however, did not move to dismiss the claims on that basis.

The district court granted respondents' motion to dismiss. Pet. App. 70a-107a. With regard to plaintiffs' Sherman Act claims, the court reasoned that a patent settlement would violate the federal antitrust laws if the parties had "entered into [the settlement] in bad faith and used the agreement to restrain or monopolize trade," *id.* at 84a, but determined that plaintiffs had failed sufficiently to allege bad faith, *id.* at 91a-98a. The court held, in the alternative, that plaintiffs had failed sufficiently to allege that they had suffered antitrust injury. *Id.* at 98a-103a. With regard to plaintiffs' antitrust claims under state law, the court noted that the parties had "agree[d] that state antitrust law should be construed similarly to federal antitrust law where possible." *Id.* at 105a. The court held that dismissal of the state antitrust claims was appropriate in light of the failure of plaintiffs' Sherman Act claim, which involved "the same allegations." *Ibid.*[4]

[4] With regard to plaintiffs' other state-law claims, the district court reasoned that those claims would be preempted by federal patent law unless they were based on respondents' bad faith, Pet. App. 106a, and again determined that plaintiffs had failed sufficiently to allege bad faith, *ibid.*

4. A divided court of appeals affirmed. Pet. App. 1a-69a, 110a-135a.

a. The court of appeals first concluded that the complaint could not state an antitrust claim based on the settlement alone "without alleging something more than the fact that Zeneca settled after it lost to Barr in the district court." Pet. App. 35a. The court reasoned that "'courts are bound to encourage' the settlement of litigation," *id.* at 29a (citation omitted), and that restrictions on patent settlements might frustrate "the goals of the patent laws because the increased number of continuing lawsuits that would result would heighten the uncertainty surrounding patents," *id.* at 30a-31a. Although the court of appeals acknowledged that a settlement could be invalid under the antitrust laws if the parties had entered into the settlement in bad faith, the court refused to consider the likelihood of success on the underlying patent infringement claim in assessing the validity of a settlement. *Id.* at 31a-32a. The court reasoned that it was impossible to assess the likelihood of Zeneca's success on appeal "with any degree of assurance." *Id.* at 32a.

The court of appeals next concluded that the mere allegation that the patent holder made a "reverse payment" to the alleged infringer as part of the settlement also did not suffice to make out an antitrust claim. Pet. App. 35a-40a. The court reasoned that "reverse payments are particularly to be expected in the drug-patent context because the Hatch-Waxman Act created an environment that encourages them." *Id.* at 37a. The court explained that a prospective generic manufacturer "has relatively little to lose" in a patent infringement suit precipitated by a paragraph IV certification, *id.* at 38a, whereas "[t]he patent holder's risk if it loses * * * is correspondingly large," *id.* at 40a.

The court of appeals rejected plaintiffs' argument that the settlement was invalid under the antitrust laws because the *size* of the reverse payment was excessive. Pet. App. 41a-53a. The court acknowledged that "[t]here is something on the face

of it that does seem 'suspicious' about a patent holder settling patent litigation against a potential generic manufacturer by paying that manufacturer more than either party anticipates the manufacturer would earn by winning the lawsuit." *Id.* at 42a. According to the court, however, "so long as the patent litigation is neither a sham nor otherwise baseless, the patent holder is seeking to arrive at a settlement in order to protect that to which it is presumably entitled: a lawful monopoly over * * * the patented product." *Id.* at 43a. The court explained that "the law allows the settlement even of suits involving weak patents with the presumption that the patent is valid and that settlement is merely an extension of the valid patent monopoly." *Id.* at 48a-49a.

The court of appeals ultimately held that, "absent an extension of the monopoly beyond the patent's scope * * * and absent fraud * * *, the question is whether the underlying infringement lawsuit was objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits." Pet. App. 52a (internal quotation marks and citation omitted). Applying that standard, the court determined that the settlement in this case was valid under the antitrust laws. *Id.* at 53a-59a.[5] The court did not separately discuss plaintiffs' state-law claims.

b. Judge Pooler dissented. Pet. App. 110a-135a. In her view, the standard of liability announced by the majority "is insufficiently protective of the consumer interests safeguarded by the Hatch-Waxman Act and the antitrust laws." *Id.* at 117a. While she "agree[d] that a settlement agreement that confers on the patent holder a greater monopoly benefit than does the patent itself is illegal," *id.* at 118a, she asserted that the "objective baselessness" prong of the majority's test was too narrow because it "ill serves the public interest in having the validity of patents litigated." *Id.* at 120a. Judge

[5] The court of appeals also held that plaintiffs' allegations that Barr had attempted to enforce the exclusivity period after the settlement had been reached did not independently state an antitrust claim. Pet. App. 53a-68a.

Pooler stated that she "s[aw] no reason why the general standard for evaluating an anti-competitive agreement, i.e., its reasonableness, should not govern in this context." *Id.* at 125a. "[I]n assessing the reasonability of a Hatch-Waxman settlement," she explained, "I would rely primarily on the strength of the patent as it appeared at the time at which the parties settled," and "secondarily on (a) the amount the patent holder paid to keep the generic manufacturer from marketing its product, (b) the amount the generic manufacturer stood to earn during its period of exclusivity, and (c) any ancillary anti-competitive effects of the agreement." *Id.* at 126a. "Because plaintiffs allege[d] that the district court's determination of patent invalidity would have been upheld on appeal; that Barr received more than it would have through a victory on appeal; and that Barr and Zeneca agreed that Barr would deploy its paragraph IV certification to defeat other potential generic entrants," Judge Pooler concluded that the complaint stated a valid antitrust claim. *Ibid.*

DISCUSSION

The petition raises important and complex issues concerning the antitrust treatment of settlements in patent cases, particularly settlements that provide for delayed entry into the market by the alleged infringer in exchange for a "reverse payment" from the patent holder. Patents by their very nature restrict competition, and the antitrust laws must be construed in a manner that avoids burdening the enforcement of legitimate patent rights. On the other hand, a settlement involving a reverse payment may restrict competition in ways that are not justified by the patent at issue, to the detriment of consumers. The court of appeals applied an insufficiently stringent standard in scrutinizing the settlement at issue here. For the reasons stated below, however, this case does not appear to present an appropriate opportunity for this Court to establish the correct standard for distinguishing legitimate patent settlements, which further the important

goals of encouraging innovation and minimizing unnecessary litigation, from illegitimate settlements that impermissibly restrain trade in violation of the antitrust laws. The petition for a writ of certiorari should therefore be denied.

I. The Petition Raises Important And Complex Issues

Although "public policy wisely encourages settlements" of legal disputes, *McDermott, Inc.* v. *AmClyde*, 511 U.S. 202, 215 (1994), it does not follow that all settlements are consistent with the antitrust laws. In most circumstances, a settlement predicated on an agreement that one party will not sell a product in competition with another party, or that it will do so only pursuant to specified terms, would likely constitute an unreasonable restraint of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. 1.

In the patent context, however, the settlement of a patent infringement claim will often involve restrictions on the sale of the product in question, and such a settlement is not necessarily impermissible or harmful to society. The Patent Act provides that "[e]very patent shall contain * * * a grant * * * of the right to exclude others from making, using, offering for sale, or selling the invention." 35 U.S.C. 154(a)(1). A valid patent thus confers on the patent holder the "right to exclude others from profiting by the patented invention." *Dawson Chem. Co.* v. *Rohm & Haas Co.*, 448 U.S. 176, 215 (1980). A patent holder can lawfully refuse to license a competitor to produce the patented article, or can grant licenses subject to exclusive territorial or other limitations. *Ibid.*; 35 U.S.C. 261, 271(d)(4); *In re Indep. Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1326 (Fed. Cir. 2000), cert. denied, 531 U.S. 1143 (2001). In many cases, the settlement of a patent infringement claim will not expand, and may even narrow, the permissible limitations on competition inherent in the patent. A patent holder may enter into such a settlement even if it believes that the likelihood that its patent will be held invalid

is relatively small, out of concern that it would suffer enormous consequences in the event of invalidation.

At the same time, competitive restraints adopted as part of a patent litigation settlement are subject to invalidation under the antitrust laws if the patent holder obtains "protection from competition which the patent law, unaided by restrictive agreements, does not afford." *United States* v. *Masonite Corp.*, 316 U.S. 265, 279 (1942). There may be particular reason to be concerned about the competitive consequences of a settlement that includes a substantial payment from the patent holder to the alleged infringer. Such a "reverse payment" can be a device for the sharing of the monopoly rents that are preserved when the alleged infringer is induced to stay out of the relevant market and drop its challenge to the validity of the patent. See Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719, 1749 (2003) (Hovenkamp); Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. Econ. 391, 408 (2003).

The Hatch-Waxman Act provides particular incentives for reverse payments in the context of settlements of patent infringement claims involving pharmaceutical products. On the one hand, as the court of appeals recognized, the Act creates incentives for such payments by authorizing and encouraging patent holders to initiate infringement litigation against prospective generic manufacturers before any actual infringement has occurred. See Pet. App. 37a-40a. Because the generic manufacturer will not have made infringing sales (that would give rise to claims for damages) or incurred production and marketing costs at the time of the infringement suit, its litigation risk will be minimal, whereas the patent holder faces potentially devastating consequences if it loses the litigation. The resulting disparity in the litigants' respective risks may tend to increase the cost of settlement for a patent holder and make reverse payments more likely, even when the patent holder's legal claims are relatively strong.

On the other hand, when a patent holder is able to settle with the first generic competitor that files an ANDA, the patent holder may be able to manipulate the 180-day exclusivity period that the Hatch-Waxman Act grants to that competitor in order to protect its own monopoly profits. Under the version of the Act in effect at the time of the relevant events here, "[i]t [wa]s widely understood that the 180-day exclusivity period" created an incentive for the parties to "settle the litigation with a 'non-entry payment' to the generic, under which the generic would delay commercialization of the generic product, thus postponing the commencement of the 180-day exclusivity period and locking other generics out of the market indefinitely." Hovenkamp 1755; see 21 U.S.C. 355(j)(5)(B)(iv) (2000).

Patent litigation settlements that include reverse payments thus implicate complex and conflicting policy considerations at the intersection of patent and antitrust law, with the Hatch-Waxman Act introducing further complexity in the pharmaceutical context. On the one hand, the interests in consumer welfare protected by the antitrust laws militate against adoption of a legal standard that would facilitate a patent holder's efforts to preserve a *weak* patent by dividing its monopoly profits with an alleged infringer. The risks are magnified in the pharmaceutical context, where the settling parties may be in a position to constrain competition from other generic manufacturers by invoking the provisions of the Hatch-Waxman Act. On the other hand, the public policy favoring settlements, and the right of a patent holder to exclude competition within the scope of its *valid* patent, would be frustrated by adoption of a legal standard that subjected patent settlements involving reverse payments to automatic or near-automatic invalidation. In the pharmaceutical context, the litigation dynamics created by the Hatch-Waxman Act may cause even a patent holder with a relatively strong claim to enter into a settlement with a reverse payment.

Those competing considerations suggest that, in the context of the Hatch-Waxman Act, the mere presence of a substantial reverse payment as part of the settlement of a patent infringement claim is not sufficient to establish that the settlement is unlawful under the Sherman Act. The correct approach is to apply the rule of reason, rather than a rule of per se legality (or illegality). Under that rule, which is "presumptively applie[d]" to claims under Section 1 of the Sherman Act, a plaintiff "must demonstrate that a particular contract or combination is in fact unreasonable and anticompetitive before it will be found unlawful." *Texaco Inc.* v. *Dagher*, 126 S. Ct. 1276, 1279 (2006). In determining whether the exclusionary effect of a settlement involving a reverse payment renders the settlement unreasonable and anticompetitive, a court at a minimum should take into account the relative likelihood of success of the parties' claims, viewed ex ante. See U.S. Br. at 11, *FTC* v. *Schering-Plough Corp.*, 126 S. Ct. 2929 (2006) (No. 06-273); cf. Hovenkamp 1759 (proposing standard that incorporates alleged infringer's "ex ante likelihood of prevailing in its infringement lawsuit").

II. The Court Of Appeals Adopted An Insufficiently Stringent Standard For Scrutinizing Patent Settlements That Include Reverse Payments

The dissenting opinion below correctly suggested that a court reviewing an antitrust challenge to a settlement of a patent infringement claim that includes a reverse payment should apply the rule of reason—and that, in doing so, a court should consider "the strength of the patent as it appeared at the time at which the parties settled." Pet. App. 125a-126a. The panel majority, however, rejected that approach and instead held that such a settlement would be valid unless (1) the settlement "extend[ed] * * * the monopoly beyond the patent's scope"; (2) the settlement involved fraud; or (3) the underlying lawsuit was "objectively baseless in the sense that no reasonable litigant could realistically expect success on the

merits." *Id.* at 52a (internal quotation marks and citation omitted). That standard is erroneous.

A. The court of appeals primarily erred by focusing on whether the underlying patent infringement claim was "objectively baseless"—a standard typically used in determining whether a defendant is entitled to antitrust immunity under the *Noerr-Pennington* doctrine—rather than engaging in a broader inquiry concerning the patent holder's likelihood of success on that claim. Pet. App. 52a. The court of appeals correctly recognized that, in passing on the validity of a settlement, a reviewing court should view the settlement from the perspective of the parties at the time they entered into it. *Id.* at 32a. The court nevertheless refused to inquire into the likelihood of success on the patent infringement claim, on the ground that it was impossible to assess the likelihood of success (in this case, Zeneca's likelihood of prevailing on appeal) "with any degree of assurance." *Ibid.* A court, however, would not need to conduct a full trial on the merits of the underlying claim in assessing the patent holder's likelihood of success, nor would a court be required to establish the likelihood of success with mathematical precision as part of the overall reasonableness inquiry. Such a limited examination of the merits of the claim (aided by the analysis of any other relevant factors surrounding the parties' negotiations) is hardly impossible. Indeed, similar inquiries are commonplace, such as in deciding whether to grant a preliminary injunction, see, *e.g.*, *Ashcroft* v. *ACLU*, 542 U.S. 656, 666 (2004), or in reviewing the fairness of a proposed class-action settlement, see, *e.g.*, *Weinberger* v. *Kendrick*, 698 F.2d 61, 74 (2d Cir. 1982) (Friendly, J.) (stating that a reviewing court must form "an intelligent and objective opinion of the probabilities of ultimate success should the claim be litigated," but need not conduct a trial) (citation omitted), cert. denied, 464 U.S. 818 (1983).

The atypical facts of this case illuminate the court of appeals' error in refusing to consider the strength of the in-

fringement claim beyond a determination that the claim was not objectively baseless. At the time the parties entered into the settlement at issue here, the district court had already held Zeneca's patent invalid in a decision on the merits.[6] As the court of appeals acknowledged, the Federal Circuit "would have reviewed [the district court's] factual findings underlying [its] conclusion of invalidity with considerable deference, rather than engaging in a presumption of validity." Pet. App. 33a (citing *Shelcore, Inc.* v. *Durham Indus., Inc.*, 745 F.2d 621, 624-625 (Fed. Cir. 1984)). Thus, this case appears to be one in which, at the time of settlement, there was reason to doubt the patent holder's likelihood of success. To be sure, the fact that Zeneca prevailed in all three of its other infringement suits presenting the identical issue might suggest that affirmance of the invalidity ruling was far from certain. The standard articulated by the court of appeals, however, precluded any such assessment.

In adopting its "objective baselessness" standard for the invalidity of patent settlements containing reverse payments, the court of appeals gave undue weight to what it viewed as the established principle that "settlement of patent litigation * * * is encouraged for a variety of reasons[,] even if it leads in some cases to the survival of monopolies created by what would otherwise be fatally weak patents." Pet. App. 51a. While it is true that the law generally encourages settlements, the Patent Act does not embody a policy of promoting the interests of patent holders at all costs. To the contrary, while designed to provide substantial incentives for true innovation,

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[6] Because the district court's decision invalidating the '516 patent would have precluded Zeneca from enforcing its patent against other generic manufacturers, the settlement between Zeneca and Barr was conditioned on vacatur of that decision. See p. 3, *supra*. As a practical matter, settlements are now unlikely to occur under similar circumstances, because this Court subsequently held that "mootness by reason of settlement does not justify vacatur of a judgment under review." *U.S. Bancorp Mortgage Co.* v. *Bonner Mall P'ship*, 513 U.S. 18, 29 (1994).

the Patent Act also reflects the "important public interest in permitting full and free competition in the use of ideas which are in reality a part of the public domain." *Lear, Inc.* v. *Adkins*, 395 U.S. 653, 670 (1969). Accordingly, this Court has repeatedly stressed the importance of definitively resolving the validity of patents, so that the public can remain free to use unpatented (or unpatentable) ideas. See, *e.g.*, *Cardinal Chem. Co.* v. *Morton Int'l, Inc.*, 508 U.S. 83, 100 (1993) (noting the "importance to the public at large of resolving questions of patent validity"); *Blonder-Tongue Labs., Inc.* v. *University of Ill. Found.*, 402 U.S. 313, 349-350 (1971) (describing the Court's "consistent view" that "the holder of a patent should not be insulated from the assertion of defenses and thus allowed to exact royalties for the use of an idea that is not in fact patentable or that is beyond the scope of the patent monopoly granted"); *Edward Katzinger Co.* v. *Chicago Metallic Mfg. Co.*, 329 U.S. 394, 400 (1947) (noting the "necessity of protecting our competitive economy by keeping open the way for interested persons to challenge the validity of patents which might be shown to be invalid"). Indeed, the Hatch-Waxman Act itself promotes that interest, by creating incentives for generic manufacturers to call into question the validity of patents by means of ANDAs with paragraph IV certifications. Particularly given the "fundamental national economic policy" in favor of competition that the federal antitrust laws promote, *National Gerimedical Hosp.* v. *Blue Cross of Kansas City*, 452 U.S. 378, 388 (1981) (citation omitted), a court considering an antitrust challenge to a patent settlement should evaluate the settlement in light of the legitimacy of the patent rights at issue in the underlying litigation.

B. The court of appeals' decision in this case is arguably in some tension with the Eleventh Circuit's decision in *FTC* v. *Schering-Plough Corp.*, 402 F.3d 1056 (2005), cert. denied, 126 S. Ct. 2929 (2006). In *Schering-Plough*, the Eleventh Circuit held that the "proper analysis" of an antitrust challenge to a patent settlement "requires an examination of:

(1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects." *Id.* at 1066 (citing *Valley Drug Co.* v. *Geneva Pharm., Inc.*, 344 F.3d 1294, 1312 (11th Cir. 2003), cert. denied, 543 U.S. 939 (2004)). Although the court of appeals in this case expressed its approval of the Eleventh Circuit's focus on whether "'the exclusionary effects of the agreement' exceed the 'scope of the patent's protection,'" Pet. App. 53a (quoting *Schering-Plough*, 402 F.3d at 1076)), the Eleventh Circuit (unlike the court of appeals here) did not purport to hold that proof of "sham" or "objectively baseless" litigation is a prerequisite to antitrust liability (in the absence of proof that the settlement extended the patent holder's monopoly beyond the patent's scope). Instead, the Eleventh Circuit did not foreclose the possibility that a party challenging a patent settlement could rely on an ex ante view of the strength of the infringement claim in contending that the settlement was invalid. As petitioners suggest (Reply Br. 2), therefore, the Eleventh Circuit's standard might permit imposition of antitrust liability in some cases in which the standard adopted below would not.[7]

III. This Case Does Not Present A Good Vehicle For Addressing The Question Presented

Although the court of appeals applied an erroneous standard for scrutinizing patent infringement settlements that

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[7] Petitioners contend (Pet. 12-13) that the court of appeals' decision also conflicts with *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896 (6th Cir. 2003), cert. denied, 543 U.S. 939 (2004), which held that an interim settlement containing a reverse payment constituted a per se violation of the antitrust laws. As the government has previously explained, however, *Cardizem* involved payments to exclude competition in drugs that did *not* fall within the scope of the allegedly infringed patent, and it is thus uncertain whether the per se rule employed by the Sixth Circuit extends beyond the unique circumstances of that case. See U.S. Br. at 16-17, *Schering-Plough*, *supra* (No. 06-273); U.S. Br. at 11-15, *Andrx Pharm., Inc.* v. *Kroger Co.*, 543 U.S. 939 (2004) (No. 03-779).

include reverse payments, this case is not an attractive vehicle for the Court's consideration of the difficult and context-sensitive questions involved in assessing the legality of such settlements. The federal antitrust claims in this case appear to be moot, the factual setting is atypical and unlikely to recur, and subsequent regulatory changes may undercut one of the theories of competitive harm advanced by petitioners. For those reasons, the petition should be denied.

A. In their complaint in this case, petitioners sought injunctive and declaratory relief under Sections 1 and 2 of the Sherman Act, 15 U.S.C. 1 and 2. See C.A. App. A64-A67. Specifically, petitioners sought "the issuance of an injunction prohibiting [respondents'] continued compliance with the terms of the unlawful Agreement[s]": *i.e.*, the settlement that terminated the patent infringement litigation. See *id.* at A67. Zeneca's patent, however, expired in 2002—and it is undisputed that the settlement ceased to have any effect at that time. As a result, an injunction prohibiting compliance with the settlement would have no operative force. Because petitioners did not seek any other equitable relief, the Sherman Act claims in this case appear to be moot. Nor, to the extent that respondents have entered into *other* similar settlements affecting petitioners (involving different drugs), could petitioners avail themselves of the exception to the mootness doctrine applicable where a controversy is capable of repetition yet evading review, because they cannot show that *those* settlements would expire before they could obtain relief. See, *e.g.*, *Spencer* v. *Kemna*, 523 U.S. 1, 17-18 (1998). There is nothing inherent in this context that would produce only settlements of brief duration.

Petitioners also sought relief under the "antitrust and/or consumer protection laws" of 21 States (and the District of Columbia) that allegedly allowed the recovery of damages by indirect purchasers. See C.A. App. A69-A75. It is unclear, however, whether or to what extent the disposition of those state-law claims would turn on resolution of the ques-

tion presented. The district court noted that the parties had "agree[d] that state antitrust law should be construed similarly to federal antitrust law where possible," Pet. App. 105a, and the court of appeals seemingly operated on that assumption in affirming the district court's dismissal of the entire action. Notably, however, petitioners have not identified even a single state statute (of the many on which the complaint relied) that has been construed as being coterminous in all respects with federal antitrust law. Indeed, the fact that the damages claims were pleaded only under state law is presumably reflective of one important difference between federal and state antitrust law: the extent to which state law allows suits for damages by indirect purchasers. While it presumably would be within this Court's discretion to grant certiorari here on the assumption that its resolution of the Sherman Act question would ultimately prove controlling, or at least informative, in the disposition of petitioners' state-law claims, cf. *Three Affiliated Tribes of the Ft. Berthold Reservation* v. *Wold Eng'g, P.C.*, 467 U.S. 138, 152 (1984), it would certainly be unusual, and potentially undesirable, for the Court to determine the scope of federal antitrust liability in a context in which the relevance of that determination to the state laws at issue is entirely uncertain.

To the extent that the state antitrust laws on which petitioners relied are *not* coterminous with federal antitrust law, moreover, this case would present a federal question only insofar as federal patent law would preempt petitioners' state-law claims. However, no preemption question is presented in the petition; preemption was not a focus of the court of appeals' analysis; and resolution of the Sherman Act question that *is* raised in the petition would not necessarily resolve the preemption issue. Nor has the preemption issue arisen in other court of appeals decisions addressing the question presented, let alone generated a circuit conflict. Because the importance and difficulty of the question presented arise out of the dynamic interplay between the federal patent and anti-

trust laws, rather than the relationship between federal patent law and state antitrust law, it would be preferable to consider that question in a case that actually involves live *federal* antitrust claims.

B. The settlement challenged in this case involves an unusual factual setting that will almost certainly not recur, and thus there is a risk that the Court's resolution of this case could turn on its unique facts in a way that would not provide clear guidance for other, more common factual settings. The government is not aware of any other Hatch-Waxman patent settlements arising after a district court judgment of *invalidity*, and none is likely to occur in the future in light of this Court's decision in *U.S. Bancorp Mortgage Co.* v. *Bonner Mall Partnership*, 513 U.S. 18 (1994), which should prevent a patent holder from obtaining vacatur of a judgment of invalidity by settling the case while the appeal is pending. The fact that the settlement at issue in this case occurred after a judgment of invalidity highlights the court of appeals' error in refusing to assess the validity of the patent, and might play a substantial role in the Court's analysis of the merits. A decision emphasizing that factor, however, might shed little light on the proper disposition of future cases challenging reverse-payment settlements in other factual settings.

C. Changes in the regulatory context have also altered the regulatory dynamic with respect to one of the theories of competitive harm advanced by petitioners, who argued in part below that Barr's agreement to assert its exclusivity rights could preclude competition from other generics. See Pet. App. 59a-68a. In 2003, Congress amended the Hatch-Waxman Act to provide for forfeiture of the 180-day exclusivity period for various reasons, including the withdrawal of a paragraph IV certification. See 21 U.S.C. 355(j)(5)(B)(iv) and (D) (Supp. IV 2004).[8] Congress also provided that any generic manufac-

[8] The statute also provides for forfeiture for failure to market a generic drug pursuant to an approved ANDA, but only after a final adjudication of patent

turer that filed an ANDA with a paragraph IV certification on the same day as the first filer would be treated as a first filer itself (and thus would be able to take advantage of the 180-day exclusivity period as against other, later filers). See 21 U.S.C. 355(j)(5)(B)(iv)(II)(BB) (Supp. IV 2004). As a practical matter, therefore, it may now be more difficult for a first-filing generic manufacturer to enter into a settlement and then use the 180-day exclusivity period effectively to lock other generic manufacturers out of the market, as Barr attempted to do in this case. Moreover, Congress specifically authorized generic manufacturers to bring "civil action[s] to obtain patent certainty" in the Hatch-Waxman context, 21 U.S.C. 355(j)(5)(C) (Supp. IV 2004), and this Court's recent decision in *MedImmune, Inc.* v. *Genentech, Inc.*, 127 S. Ct. 764 (2007), removed at least some procedural obstacles to such suits. See *Teva Pharm. USA, Inc.* v. *Novartis Pharm. Corp.*, 482 F.3d 1330, 1336-1341 (Fed. Cir. 2007). No court of appeals has addressed, in the post-2003 regulatory context, a patent settlement challenged on the ground that it will bar other generic entrants by virtue of the settling generic's exclusivity rights. To the extent the Court is inclined to address the validity of that type of settlement in particular, it may be preferable to do so in a case that arises under the current regulatory regime.[9]

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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rights, or a settlement that includes a finding of invalidity or noninfringement. 21 U.S.C. 355(j)(5)(D)(I)(bb) (Supp. IV 2004).

[9] In addition, Congress is currently considering legislation that would prohibit "reverse payments" in settlements with ANDA filers altogether. See S. 316, 110th Cong., 1st Sess. § 3 (2007); H.R. 1902, 110th Cong., 1st Sess. § 2 (2007).

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MAY 2007

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No. 06-830

IN THE

Supreme Court of the United States

In Re: TAMOXIFEN CITRATE ANTITRUST LITIGATION

JOBLOVE, ALLIED SERVS., DIV WELFARE FUND, BENNISH, KOONAN, GREAT LAKES HEALTH PLAN INC., LACAVA, DONEGA, SMITH, LOVINGER, WOOLLACOTT, WHITESIDE, PLATT, UNDERWOOD, TEAMSTERS LOCAL 237, LYNCH, CALLAWAY, MALONEY, MECHANICAL CONTRACT, IBEW-NECA LOCAL 505 HEALTH & WELFARE PLAN, A.F. OF L. – A.G.C. BUILDING TRADES WELFARE FUND, SHEET METAL WORKERS LOCAL 441 HEALTH & WELFARE PLAN, LOCAL 1199 NAT'L BENEFIT FUND FOR HEALTH AND HUMAN SERVICES, NEW YORK STATEWIDE SENIOR ACTION COUNCIL, MARKS, BLONSTEIN,

Petitioners,

v.

BARR LABS., INC., ASTRAZENCA PHARMACEUTICALS LP, ZENECA INC., ASTRAZENECA PLC,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF OF *AMICUS CURIAE* THE AMERICAN ANTITRUST INSTITUTE IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICUS CURIAE*[1]

The American Antitrust Institute ("AAI") is an independent non-profit education, research, and advocacy organization. Its mission is to advance the role of competition in the economy, protect consumers, and sustain the vitality of the antitrust laws. The Advisory Board of AAI, which serves in a consultative capacity,[2] consists of prominent antitrust lawyers, law professors, economists, and business leaders. *See http://www.antitrustinstitute.org.*

AAI's Board of Directors has authorized the filing of this brief because it believes that the Second Circuit's economic and legal reasoning is flawed and seriously threatens competition. If left standing, the opinion will undermine the careful statutory scheme that seeks to prevent weak or narrow patents from blocking the market entry of generic drugs and reducing competition. The stakes for consumers are high. The opinion will encourage and allow brand name manufacturers to pay generic competitors to keep their cheaper generic drugs off the market.

THE RELEVANT DECISIONS

Competition from generic drugs is one of the few effective means of slowing the spiraling cost of brand pharmaceuticals. Generic drugs typically sell for a fraction of the price of their brand counterparts and quickly capture the majority of unit sales, saving consumers billions of dollars on a blockbuster drug like

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[1] The written consents of all parties to the filing of this brief have been lodged with the Clerk. No counsel for a party has authored this brief in whole or in part, and no person or entity other than AAI or its counsel has made a monetary contribution to the preparation or submission of this brief.

[2] The AAI is managed by its Board of Directors. One member of the Board has recused himself from the matter. The individual views of members of the Advisory Board may differ from the positions taken by AAI. Two members of the Advisory Board have represented companies that are plaintiffs in the *Tamoxifen* case and one member has represented a defendant, but they have had no role in writing this brief.

Tamoxifen. Congress has therefore encouraged the entry of generic pharmaceuticals by, among other things, permitting generic firms to challenge the validity of pharmaceutical patents without risking infringement damages and by providing a financial bounty for successfully challenging such patents. Congress' program has been a success, with generic firms prevailing in 73% of such patent cases. Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* 16 (July 2002) [hereinafter "*Generic Drug Entry*"], *available at http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.*

Some pharmaceutical patentees have responded to these statutorily encouraged patent challenges by paying generic firms hundreds of millions of dollars to withdraw their patent challenges and stay out of the market. As explained below, these "exclusion payment" agreements have been condemned by Congress and the Federal Trade Commission ("FTC"). In the courts, however, there has been an irreconcilable split in the circuits.

It is unlawful under the Sherman Act to pay an actual or potential competitor to stay out of the market. That rule applies regardless of the degree of certainty that the potential competitor, absent the payment, would in fact enter the market. *See, e.g.*, XII Herbert Hovenkamp, ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION ¶ 2030b at 213 (2d ed. 2005); *United States v. Microsoft Corp.*, 253 F.3d 34, 79 (D.C. Cir. 2001) (*en banc*). The Court of Appeals for the Sixth Circuit therefore held in *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 914 (6th Cir. 2003), *cert. denied sub nom. Andrx Pharm., Inc. v. Kroger Co.*, 543 U.S. 939 (2004), that an exclusion payment to a generic firm to stay out of the market pending the resolution of a patent litigation is "a plain vanilla horizontal agreement to restrain trade" and unlawful *per se*. The Court reasoned that despite a rebuttable presumption of validity, 35 U.S.C. § 282, some patents are "'paper tiger[s]' incapable of deterring the generic producer from entering the

market. . . ." *Cardizem,* 332 F.3d at 915. If the patentee "had . . . been confident of the independent durability of its patent and the validity of its infringement claim, it would not have paid $89 million to effect what the patent and infringement suit had already accomplished." *Id.* The D.C. Circuit, considering the same agreement that was at issue in *Cardizem*, likewise held that it was anticompetitive. *Andrx Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 813 (D.C. Cir. 2001) (stating that an exclusion payment was "presumably in return for something that Andrx would not otherwise do, that is, delay marketing of its generic"); *see also In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d 517, 531 (D.N.J. 2004) ("It would appear obvious that this [Hatch-Waxman Act] incentive system can be distorted by cash payments made by a branded patent holder to generic manufacturers to discontinue patent validity or infringement challenges").

In the wake of the decisions in *Cardizem* and *Andrx*, a unanimous FTC similarly concluded that exclusion payments in the pharmaceutical industry are presumptively anticompetitive. *In re Schering-Plough Corp.*, FTC Docket No. 9297, 2003 WL 22989651 (F.T.C. Dec. 8, 2003). That decision, however, was vacated by the Court of Appeals for the Eleventh Circuit. *Schering Plough Corp. v. Federal Trade Commission*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006). That Court placed heavy reliance on the rebuttable presumption of patent validity. *Id.* at 1066. The generic firm's principal argument in the underlying patent litigation, however, was non-infringement. The Eleventh Circuit responded by asserting that there is also a presumption that the accused product infringes the patent in question. *Id.* ("By virtue of its '743 patent, Schering obtained the legal right to exclude Upsher and ESI from the market until they proved . . . that their products . . . did not infringe Schering's patent"). Thus, patentees can lawfully make exclusion payments to potential generic entrants regardless of whether the underlying patent litigation "turns on validity . . . as opposed to infringement." *Id.* at 1075; *see also Valley*

Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294, 1304 (11th Cir. 2003) ("A patent grants its owner the lawful right to exclude others"), *cert. denied*, 543 U.S. 934 (2004).

The decision at issue here takes the Eleventh Circuit analysis even further. The Second Circuit holds that exclusion payments are *per se lawful* unless the plaintiff proves that the underlying patent was procured by fraud or that the infringement action is a sham. Pet. App. at 42a, 51a-52a. Mere invalidity or non-infringement of the patent is insufficient to allow the exclusion payment to be challenged under the antitrust laws. The Second Circuit's analysis is founded on the rebuttable presumption of validity and on the judicial policy in favor of settling disputes. *Id.* at 48a-49a. Accordingly, although many patents are "fatally weak," *id.* at 51a, "the fact that the patent holder is paying to protect its patent monopoly, without more, [does not] establish[ ] a Sherman Act violation." *Id.* at 36a; *see also In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 536 n.21 (E.D.N.Y. 2005) ("[P]atent law imposes no such restriction against cash payments by a patent holder, and, accordingly, antitrust law does not impose such a restriction.").

The proper antitrust treatment of exclusion payments in patent settlements has also been the subject of extensive and conflicting scholarly analysis.[3] As explained below, the AAI believes it is time for this Court to resolve the issue.

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[3] For analyses suggesting that exclusion payments are anticompetitive, see Jeremy Bulow, *The Gaming of Pharmaceutical Patents*, INNOVATION POLICY AND THE ECONOMY, VOLUME 4 145, 159-73 (Adam B. Jaffe et al. eds. 2004); Joseph F. Brodley & Maureen A. O'Rourke, *Preliminary Views: Patent Settlement Agreements*, Antitrust, Summer 2002, at 53; C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement As A Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553 (2006); Herbert Hovenkamp, *Sensible Antitrust Rules for Pharmaceutical Competition*, 39 U.S.F. L. Rev. 11 (2004); Herbert Hovenkamp et al., *Balancing Ease and Accuracy in Assessing Pharmaceutical Exclusion Payments*, 88 Minn. L. Rev. 712 (2004); Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719 (2003); Cristofer

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BACKGROUND

The manner in which this issue is resolved will have enormous consequences for consumers. Patent challenges under the Hatch-Waxman Act have resulted in significant economic gains for consumers. *Generic Drug Entry*, *supra*, at 9. These gains occur when a generic firm wins a patent litigation and enters the market. In one case, the brand manufacturer refused to make an exclusion payment because it believed such a payment would violate the antitrust laws. *See* Bethany McLean,

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(Cont'd)

Leffler & Keith Leffler, *Settling the Controversy Over Patent Settlements: Payments by the Patent Holder Should Be Per Se Illegal*, 21 Res. In L. & Econ. 475 (2004); Keith Leffler & Cristofer Leffler, *Efficiency Trade-Offs in Patent Litigation Settlements: Analysis Gone Astray?*, 39 U.S.F. L. Rev. 33 (2004); Suzanne Michel, *The Right Balance of Competition Policy & Intellectual Property Law*, 46 IDEA - The Intell. Prop. L. Rev. 867 (2006); Maureen A. O'Rourke & Joseph F. Brodley, *An Incentives Approach to Patent Settlements: A Commentary on Hovenkamp, Janis and Lemley*, 87 Minn. L. Rev. 1767 (2003); Joel Schrag, *The Value of a Second Bite at the Apple: The Effect of Patent Dispute Settlements on Entry and Consumer Welfare* (Working Paper No. 281) 3-4 (2006); Carl Shapiro, *Antitrust Analysis of Patent Settlements Between Rivals*, Antitrust, Summer 2003, at 70; Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 Rand J. Econ. 391 (2003).

For analyses suggesting that exclusion payments are not unlawful, see Thomas F. Cotter, *Antitrust Implications of Patent Settlements Involving Reverse Payments: Defending a Rebuttable Presumption of Illegality in Light of Some Recent Scholarship*, 71 Antitrust L.J. 1069 (2004); Thomas F. Cotter, *Refining the "Presumptive Illegality" Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis and Lemley*, 87 Minn. L. Rev. 1789 (2003); Daniel A. Crane, *Ease Over Accuracy in Assessing Patent Settlements*, 88 Minn. L. Rev. 698 (2004); Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 Fla. L. Rev. 747 (2002); Kevin D. McDonald, *Hatch-Waxman Patent Settlements and Antitrust: On "Probabilistic" Patent Rights and False Positives*, Antitrust, Spring 2003, at 68; Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 Antitrust L.J. 1033 (2004); Robert D. Willig & John P. Bigelow, *Antitrust Policy Towards Agreements That Settle Patent Litigation*, 49 Antitrust Bull. 655 (2004).

A Bitter Pill, Fortune, Aug. 13, 2001, at 5. The patent was subsequently found invalid and the early market entry of the generic drug saved consumers an estimated $2.5 billion.[4]

Consumers also gain when patent litigation is settled in the traditional manner — with the patentee granting a license and the alleged infringer entering the market. Licensed generic entry under the Hatch-Waxman Act results in substantial consumer benefit because the generic firm can obtain market share only by selling at a significant discount to the brand price. The generic firm's incentive therefore is to negotiate for as early an entry date and as low a royalty rate as is possible in light of the merits of the patent litigation. Thus, the outcome for consumers under the license will mirror the expected (*i.e.,* risk-adjusted) outcome under litigation. In essence, licensed entry liquidates and delivers to consumers their expected gains from the patent litigation. Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 Rand J. Econ. 391, 397-99 (2003).

In contrast, an exclusion payment settlement divides the expected consumer surplus between the brand manufacturer and the generic challenger and delivers none of it to consumers.[5] *See* Herbert Hovenkamp, *Balancing Ease and Accuracy in Assessing Pharmaceutical Exclusion Payments*, 88 Minn. L. Rev. 712, 712 n.4 (2004) [hereinafter "*Balancing Ease and Accuracy*"] ("[A]n exclusion payment aligns the generic's incentives with the patentee's; they are dividing up a monopoly to which the patentee may not have been entitled"). Instead of earning profits by competing in the market, the generic firm

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[4] *See* Comment of the Generic Pharmaceutical Association in Support of Citizen Petition Docket No. 2004P-0075/CP1, at 3 (filed May 21, 2004), *available at http://www.fda.gov/ohrms/dockets/dailys/04/June04/060404/04p-0075-c00003-vol1.pdf.*

[5] Some exclusion payment settlements, including the one at issue in this case, allow entry strictly limited in time or at a very high royalty rate. Because the legal and economic issues are the same, we will for ease of reference refer to a settlement agreement that includes any exclusion payment as if it resulted in *no* generic entry.

receives a gain from the litigation, plus a share of the consumers' expected gains, in exchange for not competing. Consumers get *nothing* from the litigation. They continue to pay the higher price to the only market participant. Their expected benefit is divided between the brand manufacturer and the generic firm.

Exclusion payment settlements thus prevent consumers from obtaining expected gains from the patent litigation. The generic firm neither wins the litigation and enters the market nor uses the threat of winning to obtain a license. Instead, an exclusion payment simply divides the expected consumer benefit (*i.e.*, lower prices) between the two manufacturers.

The FTC therefore announced in March 2000 that it would aggressively prosecute exclusion payment settlement agreements. *Abbott Labs. and Geneva Pharms.*, File No. 981-0395 (Statement of FTC Chairman Robert Pitofsky and Commissioners Sheila F. Anthony, Mozelle W. Thompson, Orson Swindle and Thomas B. Leary) (Mar. 16, 2000), *available at http://www.ftc.gov/os/2000/03/ho9eschtandrxcommstmt.htm*. In response, brand manufacturers stopped entering into such agreements. From 2000 to 2004, brand manufacturers either negotiated settlements that included early generic entry via license or continued to litigate their cases. *See Prepared Statement of the Federal Trade Commission*, at 13 (Jan. 17, 2007) *available at http://www.ftc.gov/speeches/leibowitz/071701oralstatement.pdf*. [hereinafter "*FTC Prepared Statement*"]. Subsequent to the Second Circuit's decision in this case, however, the manufacturers have begun again to use exclusion payment agreements to terminate challenges to their patents. In fiscal 2006 (the Second Circuit decision issued in November 2005), nine of the eleven Hatch-Waxman settlement agreements with generic firms included exclusion payments. *See FTC Prepared Statement, supra*, at 17. A reasonable estimate of the economic impact of just one of those settlements — for the drug Provigil — is that it will cost consumers as much as

$850 million.[6] Collectively these nine settlements will cost consumers billions of dollars in higher drug prices.

In addition to transferring billions of dollars from consumers to pharmaceutical manufacturers, these exclusion payment agreements also cause substantial "deadweight loss," *i.e.*, sales not made because prices are too high. In the pharmaceutical industry, these losses have palpable, human consequences — patients who choose not to have their prescriptions filled, or who skip their medications or split their pills in half. *See, e.g.*, Thomas Rice & Karen Matsuoka, *The Impact of Cost-Sharing On Appropriate Utilization and Health Status: A Review of the Literature On Seniors*, 61 Med. Care Research & Rev. 415, 427-28 (2004). Mortality, self-reported pain, worsening medical conditions, and other adverse health effects all result from patients' decisions "not [to] comply with physicians' medication recommendations because of high costs." *Id.* at 427-28.

If exclusion payments are lawful, the economic evidence is that they will become the norm — every pharmaceutical patent case that *can* be settled *will* be settled with an exclusion payment rather than generic entry. Cristofer Leffler & Keith Leffler, *Settling the Controversy over Patent Settlements*, 21 Res. in L. & Econ. 475, 486 (2004) [hereinafter "*Settling the Controversy*"]. If the patent litigants are permitted to split the expected consumer gain from market entry and lower prices, the economic incentive is for them to do just that. *Id.* Perhaps this can be squared with the purpose of the Hatch-Waxman Act to encourage generic firms to challenge weak patents. But there are substantial arguments that it cannot, and the negative impact on American consumers should not occur without this Court's review.

This case also is important to the proper functioning of government. As explained below, the Hatch-Waxman Act's co-

[6] Provigil has annual sales of $500 million. We assume a 50 percent chance that the generic firm would have prevailed in the patent litigation, a generic penetration rate of 85 percent, a generic price 80 percent less than the brand price, and five years of damages.

authors decried the use of exclusion payments to undermine the statutory scheme and applauded the FTC's enforcement efforts. In 2002, Congress heard testimony from pharmaceutical manufacturers that exclusion payments violate the antitrust laws. Congress, therefore, enacted legislation that merely required pharmaceutical patent settlements to be reported to the FTC, which could then take appropriate enforcement action. The Eleventh and Second Circuits, however, have now concluded that the payments are not unlawful. Contradicting both Congress and the FTC, the Department of Justice ("DOJ") declined to support the FTC's effort to have the Eleventh Circuit's *Schering-Plough* decision reviewed by this Court. In short, federal policy on this issue, as articulated by Congress, the courts, and the two primary antitrust law enforcement agencies, is a shambles. This Court should grant review and resolve the controversy.

The disagreement among the three branches of government is amplified by a stark split between the Circuit courts. The Second Circuit's decision in this case has brought the divide between the Circuits to its limit. The Second Circuit now holds exclusion payments to be (with limited exceptions) *per se lawful* while the Sixth Circuit holds them to be *per se unlawful*. The Court should grant review in order to resolve this split and decide whether the procompetitive justifications offered by the Second and Eleventh Circuits have merit.

Review is also warranted by the Second Circuit's unfaithfulness to this Court's precedents recognizing the strong public interest in judicial testing of patent validity. *See, e.g., Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 100-101 (1993); *Blonder-Tongue Labs., Inc. v. University of Illinois Found.*, 402 U.S. 313, 344 (1971); *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969). That policy is reinforced here by the Congressional policy, set forth in the Hatch-Waxman Act, to encourage generic firms to judicially test pharmaceutical patents. 21 U.S.C. § 355(j)(5)(B)(iv). The Second Circuit nevertheless held that this policy is trumped by the judicial policy in favor of settling disputes. Pet. App. at 48a-49a. This Court's precedents

and the intent of the Hatch-Waxman Act establish a strong public policy in favor of the judicial testing of patents, which seems necessarily to be at odds with the Second Circuit's announced policy in favor of *avoiding* such tests.

DISCUSSION

I. THE COURT SHOULD GRANT REVIEW IN ORDER TO RESOLVE THE DIVISION BETWEEN THE THREE BRANCHES OF GOVERNMENT.

This Court should grant review to end the disharmony among the three branches of government as to the appropriate antitrust treatment of exclusion payments. And consideration of the historic timeline shows a pressing need for the Court to act now.

In careful fashion, the Hatch-Waxman Act allows generic firms to challenge weak pharmaceutical patents. Congress streamlined FDA approval of generic drugs, 21 U.S.C. § 355(j)(2)(A)(iv); provided that generic firms can challenge pharmaceutical patents without risking infringement damage liability, *id.* § 271(e)(i); and created a financial incentive for generic firms to overcome weak patents, *id.* § 355(j)(5)(B)(iv). These provisions are part of the balance reached by Congress in the Hatch-Waxman Act, which also granted to brand manufacturers patent term extensions, *id.* § 156; non-patent exclusivities, *id.* § 355(c)(3)(D)(ii) & (iii); and an automatic 30-month stay during the patent litigation, *id.* § 355(j)(5)(B)(iii).

In 1999, the FTC began three investigations against manufacturers that had used exclusion payments to terminate patent challenges. The first two resulted in consent orders,[7] and the third resulted in the unanimous FTC decision in *Schering-Plough. In re Schering-Plough Corp.*, FTC Docket No. 9297, 2003 WL 22989651 (F.T.C. Dec. 8, 2003). In the meantime, the

[7] *See Abbott Laboratories*, No. C-3945 (May 22, 2000) (Consent Order), *available at http://www.ftc.gov/os/2000/03/abbott.do.htm*; *Hoechst Marion Roussel, Inc.*, No. 9293 (May 8, 2001) (Consent Order), *available at http://www.ftc.gov/os/2001/05/hoechstdo.htm.*

Sixth Circuit had rendered its decision in *Cardizem* holding such payments to be per se unlawful. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003).

Congress closely monitored the exclusion payments controversy and held hearings on the issue. It was clear from the hearings that exclusion payments were widely condemned, including by the co-authors of the Hatch-Waxman Act. *See, e.g.*, 148 Cong. Rec. S7566 (daily ed. July 20, 2002) (remarks of Sen. Hatch) ("As coauthor of the [Hatch-Waxman Act], I can tell you that I find these types of reverse payments collusive arrangements appalling"); 146 Cong. Rec. E1538-02 (daily ed. Sept. 20, 2000) (remarks of Rep. Waxman).

In determining what action to take, Congress heard testimony from the brand manufacturers' trade association, the Pharmaceutical Research Manufacturers Association ("PhRMA"). A PhRMA representative testified that merely requiring exclusion payment agreements to be reported to the FTC was sufficient *because those payments violate the Sherman Act*:

> *Senator Dorgan*: Dr. Glover, you've heard the testimony of the chairman of the Federal Trade Commission, and I have a list of a wide range of issues here of companies that have been involved in attempting to delay or prohibit or in other ways impede the opportunity for a generic to come to the market. Are you saying that there isn't a problem here, or the problem is a small problem? . . . Is there, with respect to the behavior of some companies, according to the FTC, is there a problem in some magnitude here? And if so, what is that? Or is it your position, "This thing's working just fine. There's no problem."?
>
> *Dr. Glover*: [I]f you . . . take the facts as presented by the [FTC] as being accurate, these are circumstances [*i.e.*, the facts of *In re Cardizem CD Antitrust Litig.*, *Valley Drug Co. v. Geneva Pharm., Inc.*, and *Schering-Plough Corp.*

> *v. FTC*] where it is not going to solve the problem to change the Hatch-Waxman Act, because those cases outline facts . . . that would have been violations of the antitrust laws and/or the patent laws whether the Hatch-Waxman Act existed or not.[8]

Congress accepted PhRMA's testimony and enacted legislation that merely required exclusion agreements to be reported to the FTC.[9] The clear intent was that the FTC would prosecute and stop exclusion payments settlements. *See, e.g.*, 148 Cong. Rec. S7348 (daily ed. July 25, 2002) (remarks of Sen. Hatch) ("The FTC is doing the right thing in taking enforcement actions against those who enter into anti-competitive agreements that violate our Nation's antitrust laws"). Despite this legislative history, The Eleventh Circuit reversed the FTC's *Schering* decision. The Second Circuit similarly ruled here.

The disagreement among the governmental branches became complete when the DOJ not only declined to support the FTC's *certiorari petition* in *Schering*, but filed a separate brief disagreeing with the FTC on the merits and suggesting that the Court deny the FTC's petition.[10] While expressly disagreeing with the FTC, the DOJ's brief simply ignored Congress. The DOJ brief omitted any mention of the Hatch-Waxman Act's streamlined procedures for patent challenges, the Act's financial encouragement of such challenges, the condemnation of exclusion payments by the co-authors of the

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[8] Generic Pharmaceuticals: Marketplace Access and Consumer Issues: Hearing No. 107-1081 Before S. Comm. on Commerce, Science, and Transportation, 107th Cong. at 71 (2002) (testimony of Dr. Greg Glover).

[9] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066, at 2071.

[10] *See* Brief of the United States as Amicus Curiae in *Federal Trade Commission v. Schering-Plough Corp., et al.*, No. 05-273 (submitted May 2006), *available at www.usdoj.gov/atr/cases/f216300/216358.htm.*

Act, PhRMA's testimony that such agreements are unlawful, and the enactment of the settlement-reporting legislation consistent with that testimony.

Despite PhRMA's testimony to Congress, its members have been emboldened by the inter-branch disagreement and by the Eleventh and Second Circuit's decisions. Nine of eleven "first filer" settlement agreements reported by PhRMA's members to the FTC subsequent to the Second Circuit's decision include exclusion payments.

As this timeline shows, the current case involves a split between the Circuits and between the two agencies principally responsible for enforcing the antitrust laws. The result is that Congress has been whipsawed. The pharmaceutical manufacturers avoided Congressional action by admitting that exclusion payments are unlawful and then successfully defended those payments in court. The inter-branch disagreement has been widely noted in both the popular and professional press.[11] The fact is that "The conflicting positions presented by the FTC and the DOJ as well as the courts, have left companies and their counsel without clear guidance."[12] This Court should resolve the issue and provide needed clarity.

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[11] *See, e.g.*, Ronald W. Davis, *Reverse Payment Patent Settlements: A View into the Abyss, and a Modest Proposal*, Antitrust, Fall 2006, at 26 (noting that conflict between DOJ and FTC "is without precedent in antitrust history"); John T. Delacourt & Lee Istrail, *Schering-Plough at the Supreme Court: Justices Decline to Resolve the FTC-DOJ Dispute Regarding Reverse Payments*, theantitrustsource (October 2006), *available at www.antitrustresource.com*; Stephen Labaton, *When It Comes to Antitrust, Washington is Antibust*, Int'l Herald Trib., May 6, 2006.

[12] Strafford CLE Teleconferences, *Reverse Payment Settlements: Restraint of Trade or Legitimate Contract? Unraveling the FTC, DOJ and Federal Court Conflict* (to be held March 8, 2007), *available at http://www.straffordpub.com/products/reversepayment/ProgramOutline.pdf*.

II. THE COURT SHOULD GRANT REVIEW IN ORDER TO RESOLVE A WIDENING SPLIT BETWEEN THE CIRCUITS.

The disagreement among the governmental branches is magnified by an irreconcilable split within the Circuits. Fundamentally, this split is over how to determine the level of competition that would likely occur absent an exclusion payment.

Whether an agreement is anticompetitive is determined by comparing the amount of competition that occurs under the agreement to the amount of competition that would likely occur absent the agreement. *See Board of Trade of City of Chicago v. United States*, 246 U.S. 231, 238 (1918). In an exclusion payment case, it is known how much competition occurs under the agreement, so the issue in dispute is how much competition would likely occur in the absence of the agreement. The Sixth and D.C. Circuits, along with the FTC, assert that the proper baseline measurement is the amount of competition that the patent litigants themselves expected to occur as a result of the litigation, *i.e.*, their own views — as objectively manifested by their conduct — of the likely outcome of the litigation. *See In re Cardizem*, 332 F.3d at 915; *Andrx*, 256 F.3d at 809; *In re Schering-Plough*, 2003 WL 22989651. These authorities rely on strong economic evidence — the fact that the generic firm demanded the exclusion payment and that the brand manufacturer was willing to pay it — to show that the settlement reduced competition below the level expected by the parties. *In re Cardizem*, 332 F.3d at 915;[13] *Andrx*, 256 F.3d at 809; *In re Schering-Plough*, 2003 WL 22989651. This is consistent with the baseline measurement adopted by this Court in

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[13] As the Sixth Circuit put it, if the "independent durability of [the brand manufacturer's] patent and the validity of its infringement claim" had been sufficient on their own to exclude generic competition, then the patentee "would not have paid $89 million to effect what the patent and infringement suit had already accomplished." *In re Cardizem*, 332 F.3d at 915.

examining patent settlement agreements. *See Standard Oil Co. v. United States*, 283 U.S. 163, 171 (1931) (settlement by way of cross-licenses was lawful because it presumably reflected "a division of royalties according to the value attributed by the parties to their respective patent claims"); *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 265 (1979) (exclusionary power of patent application "depends on how likely the parties consider it to be that a valid patent will issue").

Key to these decisions is a realistic view of the exclusionary power of patents. A particular patent might be strong or it might be "a 'paper tiger' incapable of deterring the generic producer from entering the market." *In re Cardizem*, 332 F.3d at 915. The "right to exclude" conferred by a patent is not absolute and thus does not create an "impenetrable legal impediment" to competition. *Id.* at 914. Exclusion payments unlawfully "bolster the patent's effectiveness in inhibiting competitors," by transforming a limited, qualified right to exclude into a paid-for "guarantee[ ]" against competition. *In re Cardizem*, 332 F.3d at 908-907; *see also Andrx*, 256 F.3d at 813; *In re Schering-Plough*, 2003 WL 22989651, at *17.

In sharp contrast, the Eleventh and Second Circuits take a decidedly different approach to determining the competitive baseline. Relying on the statutory rebuttable presumption of patent validity and a (previously unknown) presumption of infringement, these courts assert that a patent is presumed to be valid and infringed and therefore that *no competition* was likely to occur as a result of the litigation. Pet. App. at 57a-58a; *Schering-Plough*, 402 F.3d at 1066-67. To the extent that a patent settlement allows *any* competition before the expiration of the patent, the settlement is deemed to *increase* competition as compared to the baseline of zero competition. Pet. App. at 57a-58a; *Schering-Plough*, 402 F.2d at 1067-68. The split between the Sixth and the Second Circuits is made especially sharp by the former's conclusion that exclusion payments are per se *unlawful* and the latter's conclusion that (absent sham litigation or fraud on the PTO) they are per se *lawful*.

This dichotomy invites scrutiny not only of the procompetitive justifications offered for exclusion payments, but also of the practical consequences of adopting one position or the other. If exclusion payments are permitted, *all* patent cases that can be settled will be settled with exclusion payments rather than licensed entry. *Settling the Controversy*, *supra*, at 486. If exclusion payments are not permitted, generic firms will prevail in a substantial number of cases — 73% to date — or will use that leverage to obtain licensed entry.

A Circuit split over the wisdom of permitting patentees to terminate patent challenges by purchasing the non-entry of a potential competitor clearly warrants this Court's review. *See eBay, Inc. v. MercExchange, LLC*, 126 S. Ct. 1837, 1842 (2006) (Kennedy, J., concurring) (courts must take account of the infirmities in our patent system and the "suspect validity of some . . . patents"); *see also* Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* 8 (Oct. 2003) (noting that "the PTO is underfunded, and PTO patent examiners all too often do not have sufficient time to evaluate patent applications fully"), *available at http://www.ftc.gov/os/2003/10/ innovationrpt summary.pdf*.

III. THE COURT OF APPEALS' DECISION SIGNIFICANTLY CONFLICTS WITH THIS COURT'S PRECEDENTS.

The fact that patents are often found to be invalid or not infringed has prompted this Court to hold, for more than fifty years, that the public has an overriding interest in the judicial testing of patents. The Second Circuit avoids this precedent by juxtaposing a contrary policy in favor of settlement and speculating that other, subsequently filed challenges might adequately test the patent's validity. Pet. App. at 29a-32a, 51a, 55a-58a. The Second Circuit's unfaithfulness to precedent on this issue also warrants this Court's review.

As the Court has explained, "The heart of [a patentee's] legal monopoly is *the right to invoke the State's power* to prevent

others from utilizing his discovery without his consent." *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 135 (1969) (emphasis added). In order to succeed in invoking the State's power, the patentee must defend the validity of the patent and prove infringement in court. Congress made the presumption of validity rebuttable, rather than absolute, and there is a paramount public interest in ensuring that consumers are not burdened by unwarranted patent-based monopolies. *See, e.g., Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 100-101 (1993) (Court has "emphasized the importance to the public at large of resolving questions of patent validity"); *accord*, *Blonder-Tongue Labs., Inc. v. University of Illinois Found.*, 402 U.S. 313, 344 (1971); and *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969).

With respect to pharmaceutical patents, Congress underscored this overriding public interest by providing a 180-day exclusivity bounty in order to encourage generic entry through patent litigation. *See* 21 U.S.C. § 355(j)(5)(B)(iv). Significantly, Congress did *not* create a bounty in the form of a tax break or a cash reward for merely *filing* a patent challenge — the bounty is the right to *earn profits in the marketplace by making low-priced sales*. Taking a share of the monopoly rents in exchange for ceasing efforts to enter the market is facially contrary to that Congressional intent.

The Second Circuit nevertheless relies on the general policy in favor of settlement. Pet. App. at 50a-51a. The Court asserts, without citation or analysis, that prohibiting exclusion payments will prevent "all, or nearly all, settlements of Hatch-Waxman infringement actions." Pet. App. at 50a. This unsupported factual contention is demonstrably incorrect. History establishes that prohibiting exclusion payments will merely channel settlements into lawful forms. For more than 100 years, patentees and challengers have settled cases without resorting to exclusion payments – which are an entirely recent phenomenon. *See* Herbert Hovenkamp, et al., IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW

§ 7.4e2, at 7-36 (Supp. 2007) ("Exclusion payments were not common in patent infringement litigation prior to the passage of the Hatch-Waxman amendments."). Historically, settlements simply took a different form — licensed entry. *Balancing Ease and Accuracy*, *supra*, at 716. Indeed, during the five-year period when pharmaceutical manufacturers were wary of exclusion payments (*i.e.*, after the original FTC consent orders and before the Eleventh Circuit's *Schering* decision) the drug manufacturers settled patent cases at the same rate as before. *See FTC Prepared Statement, supra,* at 13.

This view is consistent with the economic literature, which demonstrates that exclusion payments are necessary to achieve an efficient settlement in less than one-half of one percent of the possible cases. *Settling the Controversy*, *supra*, at 483-86. And those rare instances occur only when the litigants have diametrically opposed views as to the strength of the patent — a circumstance that rarely occurs. *Id.* at 485-86. This analysis is unchallenged in the volumes of economic literature on this subject.

Even if exclusion payments were necessary to settle a substantial number of patent cases, proper antitrust analysis would weigh the increased costs of litigation (if any) that results from prohibiting exclusion payments against the lost consumer welfare that results from allowing such payments. The Second Circuit made no such weighing. In pharmaceutical patent cases, however, any saved litigation costs would be utterly swamped by the lost consumer welfare. *See Balancing Ease and Accuracy*, *supra*, at 717; *see also Blonder-Tongue*, 402 U.S. at 349 (given the public interest in testing patent validity, "any reduction in litigation in this context is by comparison an incidental matter").

The Second Circuit also erroneously suggests that upholding exclusion payments does not offend the policy in favor of testing patent validity because a payment made to the first generic challenger will simply entice other generic firms to challenge the patent. Pet. App. at 55a-58a. The Court's

premise is that the prospect of obtaining the 180-day exclusivity period will motivate subsequent generic firms to challenge the patent's validity. Pet. App. at 55a (subsequent challengers will be "spurred by the additional incentive . . . of potentially securing the 180-day exclusivity"). The premise is simply incorrect. It is crystal clear that *only* the first challenger can be awarded the 180-day exclusivity. 21 U.S.C. § 355(j)(5)(B)(IV). Because subsequent challengers are not eligible for the 180-day exclusivity, a significant free-rider problem — the very problem that caused Congress to enact the 180-day bounty in the first place — blunts their incentive to aggressively attack the patent.[14]

The Second Circuit also ignores the significant entry barriers faced by subsequent challengers. These barriers include the substantial cost of developing a generic drug, the cost and time to prepare and file an ANDA, the cost and time to gain FDA tentative approval, and the Hatch-Waxman Act's automatic 30-month stay. *See Geneva Pharm. Tech. Corp. v. Barr Labs., Inc.*, 386 F.3d 485, 496 (2d Cir. 2004) ("We find evidence of particularly high barriers to entry resulting . . . from the regulatory requirements to sell generics"); *See* Herbert Hovenkamp, et al., IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW § 7.4e2, at 7-37 (Supp. 2007) ("The regulatory scheme for pharmaceutical patents means that by settling with an ANDA filer, a patent owner can delay entry by any other generic for three years or more").

The effects of the free-rider problem and the regulatory barriers were evident in the *Tamoxifen* case itself. The first generic challenger in *Tamoxifen* received its exclusion payment

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[14] Generic firms have diminished incentive to initiate costly, time-consuming challenges to the validity of patents because (absent the 180-day exclusivity) a finding of invalidity benefits not only the successful litigant, but every other potential generic manufacturer as well. *See Blonder-Tongue*, 402 U.S. at 350; Joseph Scott Miller, *Building a Better Bounty: Litigation-Stage Rewards for Defeating Patents*, 19 Berkeley Tech. L.J. 667, 725 (2004) ("[T]he free rider problem . . . undercuts [the incentive to file] definitive patent challenges").

in March 1993. The subsequent generic challengers did not obtain a Federal Circuit ruling until April 1997 — more than four years later. Pet. App. at 10a; *Zeneca Ltd. v. Novopharm Ltd.*, 111 F.3d 144 (Fed. Cir. 1997). The effects of these barriers were also evident in *Cipro*. The first challenger there received its exclusion payment in January 1997. The subsequent challengers did not get their case to even the summary judgment stage until February 2001 — more than four yeas later. *Cipro*, 363 F. Supp. 2d at 518; *Bayer AG v. Schein Pharm., Inc.*, 129 F. Supp. 2d 705 (D.N.J. 2001).

The strong public policy in favor of testing patent validity is not served by decisions that defer such testing for years. *See Cardinal Chem. Co.*, 508 U.S. at 102 (public policy forbids practices that "prolong[ ] the life of invalid patents"). This is most evident with respect to pharmaceutical patents, which can cause consumers to incur hundreds of millions of dollars *per month* in unwarranted costs. The Second Circuit's decision so far departs from this Court's precedents concerning the public interest in testing patent validity that review is warranted.

CONCLUSION

For the reasons stated above, the Court should grant the petition for review.

Respectfully submitted,

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No. 06-830

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Supreme Court of the United States

In Re: TAMOXIFEN CITRATE ANTITRUST LITIGATION

JOBLOVE, ALLIED SERVS., DIV WELFARE FUND, BENNISH, KOONAN, GREAT LAKES HEALTH PLAN INC., LACAVA, DONEGA, SMITH, LOVINGER, WOOLLACOTT, WHITESIDE, PLATT, UNDERWOOD, TEAMSTERS LOCAL 237, LYNCH, CALLAWAY, MALONEY, MECHANICAL CONTRACT, IBEW-NECA LOCAL 505 HEALTH & WELFARE PLAN, A.F. OF L. – A.G.C. BUILDING TRADES WELFARE FUND, SHEET METAL WORKERS LOCAL 441 HEALTH & WELFARE PLAN, LOCAL 1199 NAT'L BENEFIT FUND FOR HEALTH AND HUMAN SERVICES, NEW YORK STATEWIDE SENIOR ACTION COUNCIL, MARKS, BLONSTEIN,

Petitioners,

v.

BARR LABS., INC., ASTRAZENCA PHARMACEUTICALS LP, ZENECA INC., ASTRAZENECA PLC,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF OF *AMICUS CURIAE* NATIONAL ASSOCIATION OF CHAIN DRUG STORES IN SUPPORT OF PETITIONERS

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STATEMENT OF INTEREST OF AMICUS CURIAE

The National Association of Chain Drug Stores ("NACDS") is a non-profit association of nearly 200 retail pharmacy chains. NACDS members operate more than 36,000 retail community pharmacies and dispense approximately 70% of Americans' prescription drugs. Anticompetitive practices by drug manufacturers, such as the practice at issue in this case, harm NACDS members and their customers by maintaining artificially high prices for prescription drugs. NACDS believes that its industry-wide perspective on this important issue will be of assistance to the Court and therefore submits this *amicus curiae* brief in support of the petition for writ of certiorari to the United States Court of Appeals for the Second Circuit.[1]

The Second Circuit panel held that the patentee lawfully paid a challenger to withdraw its challenge to the patent and to significantly restrict competition. If left standing, that decision would undermine a careful statutory scheme in which Congress sought to rid the pharmaceutical marketplace of weak or narrow patents that block generic entry. Given the enormous consequences for consumers — consumers whose elected representatives reached a starkly different balance between the interests of patent holders and consumers — review by this Court is appropriate.

BACKGROUND

Generic entry poses a unique competitive threat to brand pharmaceuticals. Generics typically enter the market at a steep discount to the brand price, and the brand may lose as much as 70% of unit sales within the first few months after generic entry.

Manufacturers of branded pharmaceuticals therefore have a strong financial incentive to obtain patents on their products

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1. The written consents of all parties to the filing of this brief have been filed with the Clerk. No counsel for a party has authored this brief in whole or in part, and no person or entity other than *amicus curiae*, its members, or its counsel has made a monetary contribution to the preparation or submission of this brief.

and to sue generic firms to keep them out of the market. The Hatch-Waxman Act[2] encouraged generic entry by providing that the FDA cannot approve any additional generics until 180 days after the approval of the first generic whose application certified that the asserted patent is invalid or not infringed. 21 U.S.C. §355(j)(5)(B)(iv). This financial "bounty" granted by Congress for generic entry through a patent challenge can be worth hundreds of millions of dollars for the "first-filer" on blockbuster drugs. *See Teva Pharm. USA, Inc. v. FDA*, 398 F. Supp. 2d 176, 180 (D.D.C. 2005).

Congress' program of encouraging generic entry through patent challenges was a huge success. Of such cases litigated to conclusion, 73% have been resolved in favor of the generic challenger. FTC, *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, at 16 (July 2002), *available at http://www.ftc.gov/os/2002/07genericdrugstudy.pdf*; *see also* Paul Janicke & Lilan Ren, *Who Wins Patent Infringement Cases?*, 34 AIPLA Quart. J. 1, 20 (2006) (generic challengers win 70%).

Some pharmaceutical manufacturers have responded to their poor showing in these cases by paying the generic firm to withdraw the patent challenge and stay out of the market altogether, or to stay out longer than the strength of the patent warrants. By paying cash to the generic firm not to enter or to restrict entry, the patentee obtains exclusion based not on the strength of its patent, but on the strength of its capital. By accepting cash to restrict competition, the generic firm makes returns not by earning profits on sales, but by agreeing *not* to make sales in exchange for a share of the resulting monopoly rents.

The Second Circuit here nevertheless held that such "exclusion payment" settlements are (with few exceptions) per se *lawful* under Section 1 of the Sherman Act. As set forth in detail below, review by this Court is necessary because of the

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2. The Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355).

clear and irreconcilable split between the Circuits, the enormous consequences of the Second Circuit's decision for consumers, and the incompatibility of that decision with the Hatch-Waxman Act and this Court's patent law precedents.

DISCUSSION

I. The Circuits Are Split Over The Fundamental Antitrust Issue — The Proper Competitive Baseline.

The exclusion payment settlement here permitted the generic firm to enter, but with a very high royalty rate that prevented the generic product from being discounted more than 5% below the price of the branded product. Pet. App. at 58a. Absent the royalty-rate constraint, the first generic entrant typically enters at a price at 20% - 30% below the brand. In *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1059 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006), the exclusion payment agreement required the generic firm to stay out of the market altogether for more than four years. In another case, in exchange for exclusion payments of $398 million, the generic firm stayed out of the market for 6 1/2 of the remaining 7-year life of the patent. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 519 (E.D.N.Y. 2005), *appeals docketed*, Nos. 05-2851, 05-2852, 05-2863 (2d Cir.). The fundamental antitrust question raised by these cases is whether exclusion payment agreements result in less competition than is likely to result absent the exclusion payments. To answer that question, courts must estimate how much competition is likely to result absent the exclusion payments. This is the fundamental issue over which the Circuits are hopelessly split: what is the competitive baseline against which the exclusion payment settlements are properly measured?

This inquiry starts with the fact that it is uncertain whether and how much competition would result from patent litigation. Infringement determinations are usually fact intensive and subject to great uncertainty. And the question of patent invalidity is "as fugitive, impalpable, wayward, and vague a phantom as

exists in the whole paraphernalia of legal concepts." *Harries v. Air King Products Co.*, 183 F.2d 158, 162 (2d Cir. 1950) (Hand, C.J.).

The uncertainty stems in large part from the fact that patents do not receive anywhere near the scrutiny in the Patent and Trademark Office that they receive in subsequent court challenges. PTO proceedings are conducted *ex parte*, and the PTO is simply overwhelmed: "With yearly application totals approximating 300,000, they arrive at a rate of about 1,000 each working day." FTC, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, at Ch. 5 p. 4 (Oct. 2003), *available at http://ftc.gov/os/2003/10/innovationrpt.pdf*. Examiners must act quickly on these applications: "new examiners have 25 hours, and more experienced examiners have 20 hours, to examine a biotechnology patent." *Id.* at Ch. 1 p. 34.

The circumstances are radically different when the validity of a patent is challenged in court, where the proceedings are *inter se*, the court hears from opposing experts, and the issues generally receive as much time and attention as is necessary. The result is that, despite the statutory presumption of validity, 35 U.S.C. § 282, nearly half of all litigated patents are found to be invalid or unenforceable. *See* John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 206 (1998).

Against this background, courts could invoke several different possible benchmarks to determine the "but-for" amount of competition when the patentee has paid the challenger to drop the challenge and restrict competition:

First, a court could engage in a case-by-case, *ex-post* determination of patent validity and infringement as part of the subsequent antitrust case. A panel of the Eleventh Circuit appeared to require something like this in *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003), *cert. denied*, 543 U.S. 939 (2004). That Court held that an appropriate

antitrust analysis of exclusion payments requires "an identification of the protection afforded by the patent and the relevant law and consideration of the extent to which the agreements reflect a reasonable implementation of these." *Id.* at 1312. Identifying the "protection afforded by the patent" includes "consider[ation] . . . of the likelihood of the [patentee's] obtaining such protections." *Id.* On remand in *Valley Drug*, the district court conducted an exhaustive analysis of the merits of the underlying patent case and concluded that the patentee was not likely to have obtained the protection that the exclusion payments bought. *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279, 1298, 1307 n.26 (S.D. Fla. 2005). The agreement was to that extent unlawful. *Id.*

This potential baseline is subject to significant criticism. Permitting *any* type or form of settlement of a patent challenge is economically efficient only to the extent that the settlement saves litigation costs. Those costs are not saved if resolution of the patent issues is merely deferred to the subsequent antitrust case. Moreover, the deferral of the patent issues is likely to result in a significant temporal extension of the monopoly, as well as the substitution of a less capable challenger. *See* Keith Leffler et al., *Efficiency Trade-Offs In Patent Litigation Settlements: Analysis Gone Astray?*, 39 U.S.F.L. Rev. 33, 54-55 (2004) [hereinafter *"Efficiency Trade-Offs"*].

Second, courts could assume that the patent would be found to be invalid or not infringed. In the pharmaceutical industry, such an assumption is supported by the generic challengers' 73% success rate. Under this baseline, any settlement that restricted generic entry for any time or in any way would be presumptively anticompetitive. The problem with this potential baseline is that this Court has repeatedly admonished that antitrust cases should be based on marketplace realities, not legal presumptions: "[l]egal presumptions that rest on formalistic distinctions rather than actual market realities are generally disfavored in antitrust law." *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 466-67 (1992). And

although the patentees' success rate in Hatch-Waxman cases (27%) is miserable, it is not zero.

A *third* potential baseline is the patent litigants' own view of the likely outcome of the litigation, as reflected in their objective conduct. Economists use the established economic concept of "expected," *i.e.* probability-adjusted, outcomes of litigation[3] to show that the proper baseline is the amount of competition that *the parties themselves* believed, *as of the time of the agreements*, was *probable*. *See* Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719, 1758 (2003) [hereinafter "*Anticompetitive Settlement*"] (proper baseline is the "competition that the patentee could . . . expect *ex ante* to exclude after trial"); Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 Rand J. of Econ. 391, 395 (Summer 2003) [hereinafter "*Antitrust Limits*"] ("A patent settlement cannot [lawfully] lead to lower expected consumer surplus than would have arisen from ongoing litigation"). The patentee would not make a payment to the challenger unless the payment reduced competition to a level below that otherwise expected by the patentee to result from the litigation. Likewise, when the challenger requires a payment in order to agree to the entry date or royalty rate offered by the patentee, that date or rate must provide less competition than the challenger himself expects under litigation. Shapiro, *Antitrust Limits*, at 407-08; Hovenkamp, *Anticompetitive Settlement*, at 1759. This baseline takes account of the key marketplace fact that patent litigation is inherently uncertain; it focuses on the facts as of the date of the agreement; it acknowledges that the patent litigants themselves are best situated to assess the likely outcome of the litigation; and it does not require a relitigation of the patent case.

The Court used this baseline in *Standard Oil Co. (Indiana) v. United States*, 283 U.S. 163 (1931), where the parties settled

3. *See* William M. Landes, *An Economic Analysis of Courts*, 14 J. L. & Econ. 61 (1971).

a patent litigation over blocking patents by entering into a cross-license ~~agreement.~~ The Court held that the agreement was lawful because it presumably reflected "a division of royalties according to *the value attributed by the parties* to their respective patent claims. . . ." *Id.* at 171 (emphasis added); *see also Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 265 (1979) (exclusionary power of pending patent application "depends on how likely the parties consider it to be that a valid patent will issue").

With respect to exclusion payments, the Sixth Circuit has also adopted this competitive baseline. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003), *cert. denied*, 543 U.S. 939 (2004). In *Cardizem* the patentee paid the challenger to stay out of the market pending resolution of the patent litigation (the Hatch-Waxman Act automatic 30-month stay, 21 U.S.C. § 355 (j)(5)(B)(iii), had expired). Relying on marketplace realities, the Court held that a brand manufacturer's patent does not create an "'impenetrable' legal impediment to [the generic challenger's] production and sale of its FDA-approved generic product." *Cardizem*, 332 F.3d at 914. If the "independent durability of [the brand manufacturer's] patent and the validity of its infringement claim" had been sufficient on their own to exclude a generic competitor from the market, then the brand manufacturer "would not have paid [the generic competitor] $89 million to effect what the patent and infringement suit had already accomplished." *Id.* at 915. The patentee's payments gave it something that the patent did not — a "guarantee[]" against competition. *Id.* at 907.

The D.C. Circuit adopted the same baseline in *Andrx Pharm. Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 813 (D.C. Cir. 2001) ("Although its *unilateral* decision not to market its generic version of Cardizem CD would have [presumably been lawful], the counterclaim alleges that Andrx entered into an anticompetitive *agreement* with HMRI in order to exclude others; HMRI's $10 million quarterly payments were presumably in return for something that Andrx would not

otherwise do, that is, delay marketing of its generic.") (emphasis in original). So did a unanimous FTC in *In re Schering-Plough Corp.*, FTC Docket No. 9297, 2003 WL 22989651 at 17 (FTC Dec. 8, 2003) ("[I]f there has been a payment from the patent holder to the generic challenger, there must have been some offsetting consideration. Absent proof of other offsetting consideration, it is logical to conclude that the *quid pro quo* for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise."), *rev'd, Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006).

A *fourth* potential baseline is for the court applying antitrust law to assume that no competition was likely to result from the patent litigation — to assume that the patent is valid and infringed. This is essentially the baseline adopted here by the Second Circuit, which held that exclusion payments are per se lawful unless the antitrust claimant proves that the underlying patent was procured by fraud or that the patent litigation was a sham. Pet. App. at 51a - 52a. According to the Second Circuit, a patent grants to its holder a "right to exclude," which can be enforced by the patentee by paying the generic firm to withdraw its challenge to the patent. *Id.* at 28a. This is justified, according to the Second Circuit, by the rebuttable presumption of validity, 35 U.S.C. § 282. *See* Pet. App. at 48a-49a.

As noted above, this Court has repeatedly cautioned that antitrust cases must be resolved based on marketplace realities, not on formalistic assumptions. The fact that pharmaceutical patentees have lost 73% of the patent challenges would seem to rule out the Second Circuit's formalistic assumption that patentees will almost always win.

Moreover, there is no presumption of infringement. So the Second Circuit's analysis, which is founded on the presumption of validity, could not justify exclusion payments when the generic firm's challenge is based on non-infringement rather than invalidity. Nor could the Second Circuit's analysis support

the lawfulness of exclusion payments when, as is often the case, the challenge asserts that the patent is invalid if construed broadly and not infringed if construed narrowly.

The impracticality of the Second Circuit's presumption-based approach is highlighted by the Eleventh Circuit's decision in *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1075 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006). The thrust of the generic firm's challenge in *Schering* was noninfringement rather than invalidity. The Eleventh Circuit expressly recognized the impracticality of making the lawfulness of exclusion payments "turn[ ] on validity ... as opposed to infringement." *Id.* But instead of concluding that a presumption-based approach was therefore unworkable, the Court solved the problem by inventing a presumption of infringement. According to the Eleventh Circuit, "[b]y virtue of its '743 patent, Schering obtained the legal right to exclude Upsher and ESI from the market until they proved either that the '743 patent was invalid or that their products ... did not infringe Schering's patent." *Id.* at 1066-67. This is the legal abyss into which the Second Circuit's presumption-based approach inevitably leads.

* * * *

In all of the exclusion payment cases, the amount of competition that occurred under the agreements is known. The dispositive issue in each case is the "but-for" amount of competition against which the actual competition is compared. The Circuits are irreconcilably split as to the appropriate competitive baseline.

II. The Issue Is One Of Enormous Importance To Consumers.

Rarely is there as direct a connection between a judge-made rule and a profound effect on consumers as there is in this case. The reality is simple: if exclusion payments are lawful, pharmaceutical patentees will use them to terminate patent challenges that would otherwise generate *billions* of dollars in

consumer savings. These consequences to consumers — consequences to which the Second Circuit was completely inattentive — warrant review by this Court.

The enormous consumer gains resulting from generic entry are shown by a few examples. In the midst of Barr Laboratories' challenge to the patents protecting Eli Lilly's drug Prozac, Barr stated that it would settle only if the agreement included an exclusion payment of at least $200 million. *See* Bethany McLean, *A Bitter Pill*, Fortune, Aug. 2001, at 5. Lilly refused the demand because, as acknowledged by Lilly's CEO, "such a settlement violated antitrust laws, and it isn't morally right." *Id.* So Barr continued litigating the case and ultimately obtained a judgment invalidating the Prozac patents. The resulting early entry of generic Prozac saved consumers an estimated $2.5 billion.

By way of another example, a district court ruled that Apotex did not infringe GlaxoSmithKline's patent on its blockbuster drug, Paxil. *SmithKline Beecham Corp. v. Apotex Corp.*, 247 F. Supp. 2d 1011, 1052 (N.D. Ill. 2003). Apotex launched its generic Paxil product in September 2003, while the district court ruling was on appeal and more than three years before the patent was slated to expire. In April 2005, the Federal Circuit affirmed the judgment in favor of Apotex. *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1334 (Fed. Cir. 2005). Early entry of generic Paxil saved consumers more than $ 2 billion.

None of these consumer savings would likely have occurred if the Second Circuit's ruling had been the law at the time. If exclusion payments are permissible under the antitrust law — if the CEOs of Lilly and the other manufacturers are told that they are *wrong* to believe that an exclusion payment settlement "violate[s] antitrust laws, and it isn't morally right" — such settlements will very likely become the norm.

The vast majority of pharmaceutical patent cases can be settled. Leffler, *Efficiency Trade-Offs*, at 42. Of the cases that

can be settled, both the brand and generic manufacturer have a strong economic incentive to divide the monopoly profits between themselves by means of an exclusion payment rather than to share those profits with consumers by means of licensed generic entry. *Id.* at 44. Licensed entry gains far less profits for the generic than it loses for the brand, and consumers get the difference. Both parties' economic incentive, therefore, is for the brand to simply pay the generic and split the amount that licensed entry would have brought to consumers.

This economic analysis was dramatically confirmed by recent events. In connection with a consent decree obtained in one of the early exclusion payment cases, the FTC announced that it would henceforth aggressively prosecute exclusion payment pharmaceutical settlements. *Abbott Labs. and Geneva Pharms.*, No. C-3945, (FTC Mar. 16, 2000) (Statement of Chairman Robert Pitofsky and Commissioners Sheila F. Anthony, Mozelle W. Thompson, Orson Swindle and Thomas B. Leary), *available at http://www.ftc.gov/os/2000/03/hoeschtandrxcommstmt.htm.* Pharmaceutical manufacturers responded by no longer settling with exclusion payments. Instead, they settled at the same rate as they had before, but they did so the traditional way — with early-entry licenses. *See* FTC, *Prepared Statement of the Federal Trade Commission*, at 13 (Jan. 17, 2007), *available at http://www.ftc.gov/speeches/leibowitz/07170/oralstatement.pdf*. But then came the Eleventh Circuit's decision in *Schering* and the Second Circuit's decision here. The pharmaceutical manufacturers' response was swift and dramatic: in fiscal 2006, 9 of the 11 Hatch-Waxman litigation settlements with generic "first filers" included exclusion payments. *Id.* at 17. If the Second Circuit view prevails, *all* Hatch-Waxman cases that can be settled will likely be settled with exclusion payments — and the patent-challenge provisions of the Hatch-Waxman Act will be eviscerated.

While ignoring these consequences of holding exclusion payments to be lawful, the Second Circuit invented non-existent consequences of holding them to be unlawful. According to the

Second Circuit, permitting exclusion payments is necessary for society to save the costs of patent litigation. *See* Pet. App. at 50a. Three facts undercut the Court's assertion.

First, exclusion payments do not save any litigation costs to the extent that the payments merely defer rather than terminate litigation over the patent's validity. For example, here the patentee litigated the patent case through a judgment from the district court, and only then (having lost) used the exclusion payments to obtain a settlement. *Id.* at 10a. Other generic firms then challenged the patent's validity, but did not get to the same procedural point until four years later. *Id.* at 13a. Thus, the exclusion payments here *multiplied* the patent litigation costs while significantly delaying resolution of patent validity.

Second, the Second Circuit asserts, without citation or analysis, that prohibiting exclusion payments would be tantamount to prohibiting "all, or nearly all, settlements of Hatch-Waxman infringement actions." *Id.* at 50a. Economic analysis shows, however, that exclusion payments are not necessary to achieve any substantial number of efficient settlements. *See, e.g.*, Cristofer Leffler & Keith Leffler, *Settling the Controversy Over Patent Settlements: Payments by the Patent Holders Should Be Per Se Illegal*, 21 Res. L. & Econ. 475, 483-86 (2004). Indeed, exclusion payment settlements were "virtually unheard of" until this recent spate of settlements in the pharmaceutical industry. Hovenkamp, *Anticompetitive Settlement*, at 1757 n.166. Patent litigants historically have settled their cases by means of licensed entry. During the period when the FTC was successfully prosecuting exclusion payment agreements, pharmaceutical manufacturers had no difficulty at all in settling cases without exclusion payments.

Third, even if a rule permitting exclusion payments would save some litigation costs, courts should weigh those saved litigation costs against the lost consumer welfare that would result from propping up weak patents. But the Second Circuit conspicuously failed to make this essential comparison. The fact is that litigation expenses are trivial in comparison to the

lost consumer welfare that results from exclusion payments. *See* Herbert Hovenkamp et al., *Balancing Ease & Accuracy In Assessing Pharmaceutical Exclusion Payments*, 88 Minn. L. Rev. 712, 716-17 (2004) ("while patent litigation is not cheap, it is a tiny fraction of the amount of money that is at stake in the cases we are discussing"); *see also Blonder-Tongue Labs., Inc. v. University of Illinois Fnd.*, 402 U.S. 313, 349 (1971) ("the economic consequences of [permitting the patentee to repeatedly litigate validity] are serious and any reduction of litigation in this context is by comparison an incidental matter").

III. The Second Circuit's Decision Conflicts With Patent Law And The Hatch-Waxman Act.

It is unlawful under the Sherman Act to pay a competitor to restrict competition, including uncertain competition. *See, e.g., United States v. Microsoft Corp.*, 253 F.3d 34, 79 (D.C. Cir. 2001) (en banc); XII Herbert Hovenkamp, ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION, ¶ 2030b at 213 (2d ed. 2005). Here, of course, a court applying antitrust law must take account of the Hatch-Waxman Act regulatory scheme and of the fact that a patent is the source of the uncertainty of the competition. *See Verizon Communications, Inc. v. Law Offices of Curtis V. Trinko, L.L.P.*, 540 U.S. 398, 411-12 (2004). The Second Circuit's decision is entirely incompatible with patent law as reflected in no fewer than six of this Court's decisions and with Congress' specific treatment of pharmaceutical patents in the Hatch-Waxman Act.

The *Qualified* "Right to Exclude"

Relying on the rebuttable presumption of validity, the Second Circuit held that the patentee has an absolute "right to exclude" that may be enforced by paying the generic challenger to restrict competition. Pet. App. at 28a; *see also Schering*, 402 F.3d at 1066. Patent law provides no such absolute right to exclude. Instead, Congress provided for plenary judicial determination of the validity of patents. 35 U.S.C. § 282; *see Medimmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764 (2007)

(federal courts have jurisdiction to decide patent validity even when the parties have entered into a license and are complying with that agreement). As this Court has explained, "The heart of [a patentee's] legal monopoly is *the right to invoke the State's power* to prevent others from utilizing his discovery without his consent." *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 135 (1969). For example, the Court in *eBay Inc. v. Mercexchange, L.L.C.*, 126 S. Ct. 1837, 1840 (2006), held that even after a court has entered a final judgment finding infringement, the patentee is not automatically entitled to exclude the adjudged infringer, but instead must satisfy the traditional requirements for equitable relief. *See also id.* at 1842 (Kennedy, J., concurring) ("an injunction may not serve the public interest" and the "suspect validity of some of these patents may affect the calculus under the four-factor test").

The presumption of validity relied on by the Second Circuit clearly does not establish an ironclad right to exclude; it "is a procedural device, not substantive law." *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1534 (Fed. Cir. 1983). The presumption merely assigns burdens to litigants in patent trials and cannot "acquire an independent evidentiary role in any [other] proceeding." *In re Etter*, 756 F.2d 852, 856 (Fed. Cir. 1985).

The *qualified* nature of the "right to exclude" is confirmed in the Hatch-Waxman Act, where Congress did grant to patentees a procedure to obtain automatic exclusion of generic challengers, but only for a limited period of time — 30 months. After the expiration of 30 months, the FDA is free to approve a generic drug for marketing regardless of whether patent litigation is ongoing. *See* 21 U.S.C. § 355(j)(5)(B)(iii). Then the patentee can obtain exclusion only the old-fashioned way — by satisfying the requirements for a preliminary injunction, including a showing of likelihood of success on the merits.[4]

4. At the preliminary injunction stage, "the *patentee* carries the burden of showing likelihood of success on the merits with respect to

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Congress' understanding that patents are not ironclad, and that exclusion payment agreements are anticompetitive, was made perfectly clear in the hearings leading up to the pharmaceutical-settlement reporting legislation.[5] *See, e.g.*, 148 CONG. REC. S7566 (daily ed. Jul. 20, 2002) (remarks of Sen. Hatch) ("As coauthor of the [Hatch-Waxman Act], I can tell you that I find these type of reverse payment collusive arrangements appalling"); 146 CONG. REC. E1538-02 (daily ed. Sep. 20, 2000) (remarks of Rep. Waxman) ("requir[ing] companies seeking to reach secret, anticompetitive agreements to disclose them to the FTC ... [will] ensure that existing antitrust and drug approval laws are enforced to the letter"); 147 CONG. REC. S3711 (daily ed. Apr. 6, 2001) (remarks of Sen. Leahy) (legislation is intended to give to the FTC "the information they need to prevent manufacturers of patented drugs — often brand-name drugs — from simply paying generic drug companies to keep lower-cost products off the market").

The Realist View of a "Patent"

The foundation of the Second Circuit's decision is a formalist view of what a "patent" is: a patent issued by the PTO is presumed to be valid and therefore "the patent holder is [permitted to] pay [ ] to protect its patent monopoly." Pet. App. at 38a; *see also Schering*, 402 F.3d at 1068 ("there is a presumption that the '743 patent is a valid one, which gives Schering the ability to exclude [alleged infringers]"). In contrast,

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the patent's validity." *Nutrition 21 v. United States*, 930 F.2d 867, 869 (Fed. Cir. 1991) (emphasis in original); *see also Reebok Int'l Ltd. v. J. Baker, Inc.*, 32 F.3d 1552, 1556 (Fed. Cir. 1994). In pharmaceutical as well as other patent cases, courts applying patent law frequently deny preliminary injunctions on the ground that, until a judicial finding of validity and infringement, the alleged infringer has a "right to compete." *See, e.g., Illinois Tool Works, Inc. v. Grip-Pak, Inc.*, 906 F.2d 679, 684 (Fed. Cir. 1990).

5. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066.

this Court has repeatedly taken a realist, clear-eyed view of patents and the patent process. The Court has held:

> A patent, in the last analysis, simply represents a legal conclusion reached by the Patent Office. Moreover, the legal conclusion is predicated on factors as to which reasonable men can differ widely. Yet the Patent Office is often obliged to reach its decision in an *ex parte* proceeding, without the aid of the arguments which could be advanced by parties interested in proving patent invalidity.

Lear, Inc. v. Adkins, 395 U.S. 653, 670 (1969); *see also Laboratory Corp. of America Holdings v. Metabolite Labs., Inc.*, 126 S. Ct. 2921, 2929 (2006) (Breyer, J., dissenting from dismissal of certiorari) (noting the "ongoing debate . . . as to whether the patent system, as currently administered and enforced, adequately reflects the [balance embodied in the patent laws]"); *eBay*, 126 S. Ct. at 1842 (Kennedy, J., concurring) (courts determining injunctive relief should consider economic and regulatory realities).

The Public Interest

This Court has long noted that "[a] patent by its very nature is affected with a public interest" because of its potentially "far-reaching social and economic consequences." *Precision Instrument Mfg. Co. v. Automotive Maintenance Mach. Co.*, 324 U.S. 806, 816 (1945); *see also Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 100-101 (1993); *Blonder-Tongue Labs.*, 402 U.S. at 344; *Lear*, 395 U.S. at 670. The Second Circuit asserted that it had safeguarded the public interest by ensuring that the exclusion effected by the payments did not exceed the subject matter or temporal scope of the patent, assuming that the patent was valid and infringed. Pet. App. at 53a - 54a.

But the requirement alluded to by the Second Circuit — that exclusion not exceed the subject matter or temporal scope of the patent — is just "one obvious manifestation" of the principle that patents are affected with a public interest. *Blonder-*

Tongue Labs, 402 U.S. at 343. The Second Circuit ignored a second aspect of the principle — "[a] second group of authorities [that] encourage authoritative testing of patent validity." *Id.* at 344. Although patents carry a rebuttable presumption that the PTO appropriately granted the patent, *id.* at 335, "Congress has from the outset chosen to impose broad criteria of patentability while lodging in the federal courts final authority to decide that question," *id.* at 332.

Accordingly, this Court has held that a patentee cannot "muzzle[]" those who otherwise have an "economic incentive to challenge the patentability of an inventor's discovery." *Lear*, 395 U.S. at 670. That conclusion is in significant tension with the Second Circuit's endorsement of a contractual provision that simply pays the patent challenger to withdraw the challenge.

With respect to pharmaceutical patents, Congress underscored the overriding public interest in avoiding unwarranted patent-based monopolies by providing a 180-day exclusivity bounty for generic entry via patent challenges. *See* 21 U.S.C. § 355(j)(5)(B)(iv). The courts have guarded against statutory interpretations that would "diminish[] the incentive for the manufacturer of generic drugs to challenge a patent ... in the hope of bringing to market a generic competitor." *Ranbaxy Labs. Ltd. v. Leavitt*, 469 F.3d 120, 126 (D.C. Cir. 2006) (invalidating FDA rule that would have such an effect). A payment by the patentee to the generic challenger to stay out of the market is, of course, the ultimate way to "diminish[] the incentive for a [generic firm] ... [to] bring[] to market a generic competitor." *Id.*

The Initial Finding of Invalidity

The conflict between the Second Circuit's decision and this Court's patent-law precedents is heightened by the fact that the patentee here made the exclusion payments after the district court in the underlying patent litigation had already found the patent to be invalid. *See Imperial Chem. Indus., PLC v. Barr Labs., Inc.*, 795 F. Supp. 2d 619 (S.D.N.Y. 1992). That court

made key factual findings against the patentee, *id.* at 626-27, which were entitled to substantial deference on appeal. By paying off the generic challenger that had obtained the fact-driven district court judgment, the patentee wiped the factual slate clean and was able to start again against a different set of challengers. *See* Pet. App. at 12a (settlement was contingent on vacatur of district court judgment).

In contrast, this Court rejected the Federal Circuit's former practice of vacating declaratory judgments of invalidity following an appellate determination of non-infringement. *Cardinal Chemical Co.*, 508 U.S. at 102. Vacating district court judgments of invalidity "encourages endless litigation (or at least uncertainty) over the validity of outstanding patents." *Id.* Moreover, the practice tends to "multiply the opportunities for holders of invalid patents" to try to enforce them, which is particularly improper because "[i]n each successive suit the patentee enjoys the statutory presumption of validity." *Id.* at 101 n.24 (quoting *Blonder-Tongue*, 402 U.S. at 342, 338). Here the Second Circuit permitted the patentee to buy from its would-be competitor the very "multipl[e] . . . opportunities" that this Court has condemned as against public policy.

The Significance of Delay

The Second Circuit suggested that its decision is consistent with the vital policy of avoiding unwarranted patent-based monopolies because an exclusion payment made to the first generic challenger will simply invite additional challenges to the patent by other generic firms. *See* Pet. App. at 49a. The Court reached that conclusion even though the exclusion payments here resulted in a four-year delay in the judicial testing of the patent. *See id.* at 10a (exclusion payments made in March 1993, while litigants were awaiting a Federal Circuit ruling); *Zeneca Ltd. v. Novapharm Ltd.*, 111 F.3d 144 (Fed. Cir. 1997) (subsequent generic challengers did not receive Federal Circuit ruling until April 1997). Nor is this delay unusual in the pharmaceutical industry, which has substantial regulatory

barriers to generic entry. *See Geneva Pharm. Tech. Corp. v. Barr Labs., Inc.*, 386 F.3d 485, 496 (2d Cir. 2004) (noting "particularly high barriers to entry resulting . . . from the regulatory requirements to sell generics"); Herbert Hovenkamp et al., IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW § 7.4 at 7-37 (2006 Supp.) (due to regulatory barriers, exclusion payments made to first generic challenger "can delay entry by another generic for three years or more"). Exclusion payments will presumably always result in economically meaningful delay — otherwise the patentee would not make them. This Court has carefully guarded against such delay. *See, e.g., Lear*, 395 U.S. at 673 (prohibiting practice that "would give the licensor an additional economic incentive to devise every conceivable dilatory tactic in an effort to postpone the day of final judicial reckoning"); *Cardinal Chem. Co.*, 508 U.S. at 102 (prohibiting practice that "prolongs the life of invalid patents").

* * * *

In *Bonito Boats, Inc. v. Thundercraft Boats, Inc.*, 489 U.S. 141 (1989), the Court held that the State of Florida could not properly create patent-like rights that are broader than those embodied in the federal patent law. Such non-federal exclusionary rights are impermissible because "the federal patent laws have embodied a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy." *Id.* at 146; *see also Laboratory Corp.*, 126 S. Ct. at 2922 (Breyer, J., dissenting from dismissal of certiorari) ("patent law seeks to avoid the damage of overprotection just as surely as it seeks to avoid the diminished incentive to invent that underprotection can threaten").

Imagine if, instead, Florida enacted a statute providing that its courts would grant preliminary and permanent injunctive relief in favor of patentees without inquiry into the validity of

the patent (or inquiry limited to whether the patent was so obviously invalid as to render attempted enforcement a "sham"). Imagine further that Florida attempted to justify its statute on the grounds that patents once issued by the PTO are presumed to be valid and that the policy of the federal government is to save litigation costs. Against the background of this Court's patent precedents, is it not clear that Florida's attempts to justify its statute would be met with incredulity? And would not the incredulity turn to astonishment if the Florida statute purported to apply even after a federal district court had found a patent to be invalid?

Yet the Second Circuit's decision here permits private parties to do exactly what no State would be permitted to do. That decision is irreconcilable with this Court's fundamental patent precedents and with the Hatch-Waxman Act, and the Court should therefore grant review.

CONCLUSION

NACDS respectfully submits that this Court should grant certiorari to resolve a Circuit split on a matter of enormous consequence to consumers, and to conform the law on this issue with the Court's patent-law precedents and the Hatch-Waxman Act.

Respectfully submitted,

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No. 06-830

IN THE

Supreme Court of the United States

In Re: TAMOXIFEN CITRATE ANTITRUST LITIGATION

JOBLOVE, ALLIED SERVS., DIV WELFARE FUND, BENNISH, KOONAN, GREAT LAKES HEALTH PLAN INC., LACAVA, DONEGA, SMITH, LOVINGER, WOOLLACOTT, WHITESIDE, PLATT, UNDERWOOD, TEAMSTERS LOCAL 237, LYNCH, CALLAWAY, MALONEY, MECHANICAL CONTRACT, IBEW-NECA LOCAL 505 HEALTH & WELFARE PLAN, A.F. OF L. – A.G.C. BUILDING TRADES WELFARE FUND, SHEET METAL WORKERS LOCAL 441 HEALTH & WELFARE PLAN, LOCAL 1199 NAT'L BENEFIT FUND FOR HEALTH AND HUMAN SERVICES, NEW YORK STATEWIDE SENIOR ACTION COUNCIL, MARKS, BLONSTEIN,

Petitioners,

v.

BARR LABS., INC., ASTRAZENCA PHARMACEUTICALS LP, ZENECA INC., ASTRAZENECA PLC,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF AMICI CURIAE OF 41 PROFESSORS OF ECONOMICS, BUSINESS AND LAW IN SUPPORT OF GRANTING THE PETITION

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INTEREST OF AMICI

Amici are professors of business, economics and law who have written extensively on innovation, intellectual property, competition and antitrust. Amici have no stake in the outcome of this case.[1] (A list of signatories is in Appendix A). Our sole interest in this case is that patent and antitrust law develop in a way that serves the public interest and public health by promoting both innovation and competition.

ARGUMENT

I. The Second Circuit Opinion Is Unprecedented and Conflicts With the Approaches of the Sixth Circuit, the Eleventh Circuit, and the Federal Trade Commission

The Second Circuit's opinion in this case contains fundamental errors of economic reasoning and would shield many anti-competitive agreements from the reach of antitrust law, causing great harm to competition, to U.S. consumers, and (by unjustifiably raising the costs of needed medicines) to public health. According to the panel majority, an agreement between a patent holder and an alleged infringer to settle their patent litigation cannot violate the antitrust laws so long as the patent litigation was not a sham or otherwise baseless and the settlement agreement does not impose restrictions on the alleged infringer that extend beyond the scope of the patent. Such settlements are considered *per se* legal even if, as here, the patent holder makes a substantial payment to the alleged infringer in exchange for the latter's promise not to sell the patented product independently during the patent's lifetime, and even if the patent in question is "fatally weak." *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 212 (2d Cir. 2006). In so holding, the panel majority has adopted a rule of near per se *legality* for conduct that seems anticompetitive on its face.

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1. We certify that no party other than the signatories has paid for or participated in the drafting of this brief. We have received the consent of all parties to the filing of this brief.

The panel's rule is far outside the mainstream of judicial and academic analysis of settlements that involve such payments and promises ("exclusionary settlements"). The Sixth Circuit considers such agreements per se *illegal*, *see In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003), the Federal Trade Commission considers them presumptively anticompetitive, *see In re Schering Plough Corp.*, No. 9297 (F.T.C. Dec. 18, 2003), *rev'd*, 402 F.3d 1056 (11th Cir. 2005), while the Eleventh Circuit applies its own test that inquires into the underlying validity of the patent before characterizing the conduct, *see Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294 (11th Cir. 2003). No other circuit has applied the panel majority's approach. Similarly, although academic commentators are divided on the treatment to be accorded such settlements, they uniformly agree they should not be consider per se *legal*. Some, including some of the undersigned, have written that settlements involving a large payment from the patent holder to the challenger should be presumptively anti-competitive.[2] Others have argued for applying the rule of reason[3] or for

2. *See, e.g.*, 1 *Herbert Hovenkamp et al., IP and Antitrust* §7.4e2, at 7-38 to 39 (2005 Supp.); Scott A. Hemphill, "Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem," 81 *NYU L. Rev.* 1553 (2006); Herbert Hovenkamp et al., "Anticompetitive Settlement of Intellectual Property Disputes," 87 *Minn. L. Rev.* 1719 (2003); Carl Shapiro, "Antitrust Limits to Patent Settlements," 34 *Rand J. Econ.* 391 (2003); Jeremy Bulow, "The Gaming of Pharmaceutical Patents," in 4 *Innovation Policy and the Economy*, (Adam B. Jaffe et al. eds. 2004); Mark A. Lemley & Carl Shapiro, "Probabilistic Patents," 19 *J. Econ. Perspectives* 75 (2005); Joseph Farrell & Carl Shapiro, "How Strong Are Weak Patents?" Competition Policy Center Working Paper 05-054 (2005), available at *http://repositories.cdlib.org/iber/cpc/CPC05-54/*.

3. Daniel A. Crane, "Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications," 54 *Fla. L. Rev.* 747, 779-96 (2002); Roger D. Blair & Thomas F. Cotter, "Are Settlements of Patent Disputes Illegal Per Se?", 47 *Antitrust Bull.* 491, 534-38 (2002).

per se illegality.[4] Other courts and commentators note that the antitrust analysis is more complex for settlements that generate offsetting benefits to consumers, e.g., those involving negotiated entry dates or patent licenses.[5] It is ironic that the panel majority—the first Court of Appeals to apply such a rule—justified its unprecedented decision by saying that "[i]t is too late in the journey for us to alter course." *Id.* To the contrary, it is the panel majority that sets out on a new and dangerous course.

The amici differ in their views on precisely what standard should be applied to judge the legality of exclusionary settlements. We need not resolve those differences in this case because we all agree that exclusionary settlements can state a claim under the antitrust laws. The panel majority took the unprecedented step of concluding on a motion to dismiss that exclusionary settlements can almost never be illegal. As a result, unless the opinion is reversed case law in the Second Circuit will never develop to distinguish pro- and anti-competitive settlements. Worse, without review by this Court businesses will lack guidance on the legality of their conduct because fundamental conflicts between the approaches of the different circuits will persist.

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4. Maureen A. O'Rourke & Joseph F. Brodley, "An Incentives Approach to Patent Settlements," 87 *Minn. L. Rev.* 1767, 1781-82 (2003).

5. *Schering Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005) (finding that a cross-license agreement did not violate the antitrust laws); 1 *Hovenkamp et al., supra* note 2, at §7.4e3 (discussing delayed entry settlements).

II. Exclusion Payments Are Generally Anticompetitive

A. The Settling Parties Have an Incentive to Preserve Monopoly Profits in Ways That Harm Consumers, Competition, and Public Health

A monopolist and any uniquely strong or early-arriving potential entrant have a strong incentive to enter into an exclusionary settlement. The settlement preserves the monopoly and thus keeps prices and profits high. In the Hatch-Waxman setting, where the first generic to file an ANDA is entitled to a period of statutory exclusivity, the patent owner's incentive to settle with that first generic is particularly great.

The fact that the *parties* to the settlement can maximize their profits through an exclusion payment does not mean that such a settlement is in the *public* interest. That extra profit comes from somewhere. In the case of an exclusionary settlement under the Hatch-Waxman Act, it comes from the pockets of the elderly and other users of medicines who would be able to purchase lower cost medications if the generic's legal arguments were successful. Absent the settlement, the patent litigation might reveal that the patent was invalid or not infringed, leading to more competition and lower prices. With an exclusion payment, the pharmaceutical patentee buys assurance that its patent will not be invalidated—something the patent law alone does not give and that the Hatch Waxman Act did not contemplate. It uses some of this extra monopoly profit obtained by avoiding what might have been a successful legal challenge to pay off the potential competitor. Such a settlement denies consumers the benefits of enhanced competition that Congress intended to result if the patent were found invalid or not infringed. Those benefits aren't merely a windfall from abrogation of a legitimate patent. On the contrary, they result from the right to invalidate patents the government should never have issued. Discovering the truth about the patent's validity or scope in no way threatens the rewards to properly patented innovations that in fact are infringed.

Under the panel majority's opinion, the monopolist and potential entrant are permitted to enter into an exclusionary settlement that denies these benefits to consumers *regardless* of contemporaneous evidence about the likelihood that the patent will be found invalid or not infringed. In particular, the majority ignored evidence in the form of a large exclusionary payment from the patent holder to the potential rival, surely an indication that the patent holder considered its patent to be weak. The panel even ignored the fact that at the time of settlement the patent in question had been held invalid in the district court. The interests of consumers are given no weight at all in the majority opinion's calculus. Nor is the public interest in testing weak patents given any weight at all.

B. The Panel Majority Wrongly Assumes That Every Patent Holder Has an Absolute Right to a Monopoly

The panel majority acknowledges that "there is something on the face of it that does seem 'suspicious'" about a large reverse payment, *Tamoxifen Citrate*, 466 F.3d at 208, but goes on to say:

> We think, however, that the suspicion abates upon reflection. In such a case, so long as the patent litigation is neither a sham nor otherwise baseless, the patent holder is seeking to arrive at a settlement in order to protect that to which it is presumably entitled: a lawful monopoly over the manufacture and distribution of the patented product.

Id.

Here and at other key points, the majority falls back on the *assumption* that the patent holder, by virtue of the patent grant, has an absolute right to enter into an exclusionary settlement, simply because of the presumption of validity afforded to patents. But that assumption is false. A patent

does not confer a certain legal right. *In re Etter*, 756 F.2d 852, 856 (Fed. Cir. 1985). Rather, it reflects an initial judgment by the Patent and Trademark Office that the invention is patentable. That judgment is made after only a cursory scrutiny. When a patent is asserted in litigation, accused infringers are entitled to demonstrate that the patent should not have issued. As this Court put it in *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969):

> A patent, in the last analysis, simply represents a legal conclusion reached by the Patent Office. Moreover, the legal conclusion is predicated on factors as to which reasonable men can differ widely. Yet the Patent Office is often obliged to reach its decision in an ex parte proceeding, without the aid of the arguments which could be advanced by parties interested in proving patent invalidity. Consequently, it does not seem to us to be unfair to require a patentee to defend the Patent Office's judgment when his licensee places the question in issue ...

Id. at 670. Virtually every accused infringer asserts invalidity, and nearly half of all litigated patents are ultimately found invalid.[6] The number is even higher in pharmaceutical cases – an FTC study of all pharmaceutical patent litigation between 1992 and 2000 found that the patent owner lost in 73% of the cases. *http://ftc.gov/os/2006/07/P052103BarrierstoGeneric EntryTestimonySenate07202006.pdf* (page 10). Further, in cases such as this one, the fact that the patent owner must pay the accused infringer a large sum of money to stay out of the market – or even just to delay entry – is strong evidence that the patent owner sees the patent as likely to be held invalid or not infringed. The patent holder in such situations rationally understands that to protect the value of a monopoly *to which it*

6. John R. Allison & Mark A. Lemley, "Empirical Evidence on the Validity of Litigated Patents," 29 *Am. Intell. Prop. L. Ass'n. Q.J.* 185 (1998) (studying all patent validity litigation over an 8-year period and finding that 46% of all patents litigated to judgment were held invalid).

was never in fact and in law entitled, it must share some of the ill-gotten revenue with those who would otherwise invalidate it. They in turn have every incentive to settle in exchange for a share of the monopoly profits rather than to litigate.[7]

Where, as here, the case arises on a motion to dismiss, the courts must take as true plaintiffs' allegations that the Federal Circuit would likely have affirmed the district court's initial finding that the patent was invalid. If the patent can be proven invalid, the settlement can certainly be anticompetitive and thus should be subject to antitrust review.

The panel majority does not merely protect established rights of patent holders. Rather, by letting patent owners buy immunity from competition even with "fatally weak" patents, the majority has greatly expanded the patent holders' rights, turning a rebuttable (and often-rebutted) presumption into an irrebuttable one. A presumption of validity does not entitle a patentee to evade the test of patent litigation, any more than a criminal defendant's presumption of innocence entitles him to avoid trial. Allowing holders of weak patents thus to boost their profits is a poor way to encourage innovation, because by definition a weak patent often reflects no truly patentable innovation by the patentee. This Court has recognized "the important public interest in permitting full and free competition in the use of ideas which are in reality a part of the public domain." *Lear*, 395 U.S. at 670. That interest would be ill-served by allowing patentees to avoid any scrutiny of the validity or scope of application of their patents simply by agreeing to split their unwarranted profits with those who would challenge their right to those profits.

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7. Because the generic competitor can charge only a competitive price, it is possible for a settlement to provide a share of the monopoly price profits that convey to the generic competitor even greater profits than would be achieved by a successful lawsuit. Thus, the generic by settling avoids both litigation and commercial risks with higher potential returns – all at the expense of the consumer.

C. Permitting Exclusion Payments Is Not Necessary To Encourage Settlements in the Public Interest

The panel majority recognized that its rule shields troubling settlements from the antitrust laws, but concludes that the policy favoring settlement is so strong that it must extend even to "fatally weak" patents, "even though such settlements will inevitably protect patent monopolies that are, perhaps, undeserved." *Tamoxifen Citrate*, 466 F.3d at 211.

We agree that there is a general policy in favor of settlement. We strongly disagree, however, with the majority's view that patent settlements must *always* be encouraged. That view confuses a general policy in favor of settlements that are in the public interest with an endorsement of a particular kind of settlement despite evidence that it is not in the public interest because of its anticompetitive effects. The general preference for settlement over litigation must be tempered when settlements have important adverse effects on third parties; in the language of economics, there is no good reason to encourage settlements that impose significant negative externalities. Patent litigation serves the crucial role of testing weak patents and protecting the public from monopolies based on invalid patents. The social benefit of invalidating weak patents is well established in a line of this Court's cases. *See, e.g., United States v. Glaxo Group, Ltd.*, 410 U.S. 52, 57 (1973); *Blonder-Tongue Labs. v. Univ. of Illinois Found.*, 402 U.S. 313 (1971); *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969); *see also Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 264 (1979) (referring to the "desirability of encouraging licensees to challenge the validity of patents"). A successful patent challenge provides valuable (and in the case of medicines necessary) benefits to third parties, including anyone who seeks to practice the patented

technology and consumers via enhanced competition.[8] The majority's rule dramatically undermines the important role of patent litigation in protecting the public from undeserved monopolies based on patents that may well prove to be invalid.

Reversing the panel majority's unprecedented and unwise rule of per se legality would by no means subject every patent settlement to an antitrust challenge. As noted above, some (including some of us) have suggested that a large exclusionary payment could be a suitable red flag, providing a limiting principle on such challenges; experience over time might suggest other approaches, but no such evolution can occur in the Second Circuit if the majority's holding stands.[9] The public interests involved warrant judicial evaluation of the facts of particular cases, and (if the Second Circuit holding is reversed) the courts can develop additional rules to provide guidance and to limit the burdens on the courts.

The majority is also wrong to assume that immunizing exclusion payments is necessary to encourage the many settlements that are in the public interest. Both generally and in the pharmaceutical context, patent owners and generics can and do settle patent cases without exclusion payments,

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8. *See, e.g.*, Joseph Farrell and Robert Merges, "Incentives to Challenge and Defend Patents: Why Litigation Won't Reliably Fix Patent Office Errors and Why Administrative Patent Review Might Help," 19 *Berkeley Tech L.J.* 943 (2004); Joseph Scott Miller, "Building a Better Bounty: Litigation-Stage Rewards for Defeating Patents," 19 *Berkeley Tech. L.J.* 667 (2004).

9. Nor could the Federal Trade Commission, the expert agency with jurisdiction over pharmaceutical patent settlements, develop such a rule. Because decisions of the Commission may be appealed to any regional circuit in which the defendant conducts business, Federal Trade Commission Act §5(c), if the Second Circuit's decision is allowed to stand the United States will effectively be subject to the rule of per se legality in all its cases involving exclusion payments.

by agreeing to let the generic enter in exchange for a license fee, by agreeing to delay entry without a payment, or in other ways. Indeed, the Federal Trade Commission, to which pharmaceutical patent settlements must now be reported, found 14 agreements settling patent litigation during 2003 and 2004, with none involving an exclusion payment. *See http://www.ftc.gov/opa/2005/01/drugsettlement.htm.* The fact that pharmaceutical companies can and do settle litigation without exclusion payments shows that there is no need to allow anticompetitive settlements in order to get the social benefits that most settlements provide.

III. This Case Presents a Question of Extraordinary Importance

This Court has long recognized that decisions on the validity of patents implicate important public interests. *Precision Instrument Mfg. Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806, 816 (1945) ("A patent by its very nature is affected with a public interest."); *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172, 177 (1965); *Pope Manufacturing Co. v. Gormully*, 144 U.S. 224, 234 (1892) ("It is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly."). Nowhere is that more true than in the area of pharmaceuticals. Consumers pay literally tens of billions of dollars more for patented drugs than they would for the same drugs if unpatented. Numerous studies have shown that higher drug prices result in consumers having to forego needed medicines. One study found that among people 65 and older, "a one-dollar increase in the out-of-pocket per tablet cost resulted in the purchase of 114 fewer tablets per year."[10]

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10. Jan Blustein, *Drug Coverage and Drug Purchases by Medicare Beneficiaries with Hypertension*, 19 Health Aff. 219, 228 (Cont'd)

Where those patents are validly granted, the monopoly price arguably reflects a needed incentive to innovation. But where, as alleged in this case, a patent owner insulated a "fatally weak" patent from judicial scrutiny by entering into an anticompetitive agreement to avoid invalidation, it is the public that bears the cost of an *improperly* obtained monopoly on needed medicines. Anticompetitive settlements of this sort are all too common, and violate the legislative purpose behind the Hatch-Waxman Act, which was in part to encourage generic manufacturers to challenge weak patents. They will continue to proliferate unless and until the courts recognize the potential for anticompetitive harm and apply the antitrust laws accordingly. And in light of the Second Circuit's ruling in this case, only Supreme Court review can make that happen.

CONCLUSION

We urge the Court to grant certiorari and to reverse the decision of the Second Circuit Court of Appeals.

Respectfully submitted,

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(Cont'd)

(2000); *see also* Kaiser Family Foundation et al., *National Survey on Prescription Drugs* 4 (Sept. 2000) (reporting that 9% of U.S. citizens 65 and older have had to cut down on food or other basic necessities to pay for prescription drugs), *available at* http://www.pbs.org/newshour/health/prescriptions/summaryandchartpack.pdf.

APPENDIX

APPENDIX

List of Signatories[1]

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